ALFRED CALLAHAN, III, M.D. RUFFINO vs ARCHER

IVOLLINO AS AIVOLIFIX				
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NASHVILLE DIVISION	3 4	By Mr. Gideon		4
JOHN RUFFINO and MARTHA	5			
	6	NUMBER	DESCRIPTION PAG	E
RUFFINO, Husband and	ľ	Exhibit No. 1	December 8, 2017,	
Wife,	7 8	Debibit No. 0	Letter	:
Plaintiffs, Civil Action	No. 8	Exhibit No. 2 Exhibit No. 3	Handwritten Notes Handwritten Note on	2
3:17-cv-0072			Envelope	
v.	10	Exhibit No. 4	Article Titled: Acute	4
Jury Demand	11	EMILDIC NO. 1	cigarette smoke	-
DR. CLARK ARCHER and HCA Judge Campbe.	11 12		exposure reduces clot lysis - association	
HEALTH SERVICES OF Magistrate Ju			between altered fibrin	
TENNESSEE, INC. D/b/a Newbern	13		architecture and the	
STONECREST MEDICAL	14		response to tPA	
		Exhibit No. 5	November 24, 2015,	61
CENTER,	15		Medical Record by Dr. Luck	
Defendants.	16		DI. HUCK	
DEPOSITION OF ALFRED CALLAHAN, III, M.D.	1.5	Exhibit No. 6	February 17, 2016,	62
April 18, 2018	17		Centennial Medical Record	
Deposition of ALFRED CALLAHAN, III	, 18			
M.D., taken at the offices of Dr. Callahan,	19	Exhibit No. 7	Medical Record Dated February 18, 2016	93
2000 Glen Echo Road, Suite 122, Nashville,	20	Exhibit No. 8	Medical Record Dated	9'
Tennessee, at 1 p.m. (CST) on the above date	0.1		February 20, 2016	
before Stephanie A. Faulkner, LCR, CRI, CPE,	21	Exhibit No. 9	Medical Record Dated	10
	22		February 26, 2016	
Tennessee Licensed Court Reporter, pursuant	23 24	Exhibit No. 10	Handwritten Notes	121
to the Federal Rules of Civil Procedure.	25			
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1 APPEARANCES	1	ALFRE	ED CALLAHAN, III, M.D	
On Behalf of the Plaintiffs:	2	having been fi	rst duly sworn, testified	as
3	3	-	,	
Mr. Brian Cummings	4		RECT EXAMINATION	
4 Attorney at Law Cummings Manookian, PLC	5	BY MR. GIDE	-	
5 45 Music Square West	-		OIN.	
Nashville, TN 37203			allahara sasa tama ta aal	
(15 266 2222	6	Q. Dr. C	allahan, my turn to ask	you
6 615-266-3333 bcummings@cummingsmanookian.com	7	Q. Dr. C questions.		you
bcummings@cummingsmanookian.com	-	Q. Dr. C		you
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Page 5 Page 7 1 an explanation. If I do that, I hope you 1 smaller as the years have gone by, and it 2 started off small to begin with. 2 won't be offended. 3 Α. I will not be. 3 Did you prepare any notes as you reviewed the imaging at StoneCrest and the 4 Q. Okay. Have you done all you need 5 to do to form your opinions in this case? imaging at Centennial? 6 6 Α. Yes, sir, I did. 7 7 Q. Okay. When were you first engaged? All right. I think probably the 8 And you're free to look at this, if you wish 8 best thing to do is for you to identify your 9 to, the first contact. 9 notes that address your reviews of the 10 imaging. We'll exhibit those notes. And I 10 It's my recollection that Α. 11 Mr. Cummings called me in August of last 11 know there's a separate pages, Dr. Callahan, 12 year, 2017. 12 of notes where you describe imaging at 13 Tennova, which it appears you got later, 13 What did he ask you to do? Q. 14 Α. To look at a case. 14 right? All right. Did you know it had 15 A. Yes. I received that very 15 Q. 16 already been filed? 16 recently. 17 Q. Right. And by that, we're 17 A. I don't know if he told me that, 18 referring to the December 23, 2015, MRI and 18 so... 19 Q. Now, there is a letter in those 19 MRA at University Medical Center in Lebanon, 20 correct? 20 materials that's dated in December of 2017, 21 if you could put your hands on that. And I 21 Α. Yes. 22 think that is the first written communication 22 Q. Okay. Any other recent imaging you 23 that's dated in those materials. Will you 23 received? 24 check and see if that's correct? I think 24 Α. 25 it's clipped on the outside of that envelope. 25 Q. By the way, have you ever received Page 6 Page 8 I believe you're right. a copy of the affidavit of Jodi Dodds, the 1 Α. 2 Q. What's the date? vascular neurologist at Duke? A. I don't recall if -- I think I may 3 A. Of that letter? 3 4 Q. Yes. have read that electronically. A. 08 December '17. 5 5 Do you think you did? Q. 6 MR. GIDEON: We'll make the 6 Α. I think I did. 7 7 December 8, 2017 letter Exhibit 1. Okay. Have you seen the disclosure 8 of opinion testimony by Jodi Dodds and a (Whereupon, the above-mentioned 8 document was marked as Exhibit No. 1 to the Dr. Zazulia from Washington University in 10 St. Louis on our behalf? 10 testimony of the witness.) 11 BY MR. GIDEON: 11 Α. I don't recall that. Q. What was included with the letter 12 Q. Okay. All right. In any event, 12 13 of December 8th, 2017 in terms of substantive 13 let's get back to the notes. How many pages 14 materials for you to review? 14 of notes do you have just describing the My recollection was that I had 15 imaging? 15 16 gotten a CD of imaging with the letter. 16 Α. One page. 17 Q. Okay. Was the imaging limited to 17 Q. Front and back? 18 the CT scan and the CTA at StoneCrest? 18 Α. No. Just this side. 19 No. There were -- there were two 19 MR. GIDEON: Okay. We're going to Α. 20 discs. So one was from StoneCrest with 20 make this one page that he's going to be 21 imaging and the other was from Centennial reading from an exhibit. We'll make this one 21 22 page Exhibit 2. 22 with imaging. 23 23 All right. Okay. As I mentioned (Whereupon, the above-mentioned 24 to you before we began the deposition, I 24 document was marked as Exhibit No. 2 to the

25 swear your handwriting has gotten actually

25 testimony of the witness.)

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Page 9 Page 11 1 BY MR. GIDEON: 1 Q. Okay. Q. Now, Dr. Callahan, would you just 2 2 A. Same as TIMI. You know, they're 3 analogous. 3 read your notes, please, of the 4 interpretation of the imaging? Tell us what And the goal of a bunch of studies 4 5 study you're looking at first, and then tell that we will talk about later today is to 6 us what you thought of it. achieve reperfusion to a two B or three 7 The page begins, Ruffino imaging; 7 level, correct? 8 CD, StoneCrest. CT head plain 2/17/16 1027 8 Yes. A. 9 hours. Calcification of the left vertebral 9 Q. Okay. 10 artery, right internal carotid artery, and a 10 A. On an urgent basis. 11 large cisterna magna. No hyperdense MCA. No 11 Right. Are you finished with the Q. 12 certain changes. 12 CTA interpretation? 13 Q. Okay. 13 A. Yes. 14 A. Want me to continue? 14 Q. Okay. Were you able to actually 15 Is that it as far as the CT scan see an acute thrombus or embolus in the M1 or 16 that was done at approximately 10:30 in the M2 branch of the MCA? 16 17 morning? 17 A. No. 18 A. Yes. 18 Q. Okay. Where was the occlusion? 19 Q. Okay. Now, what about the CTA in 19 Α. I think it's in the mid portion of 20 the afternoon? 20 the left M1 segment. 21 The notes goes on to say, CTAH, 21 And when it's in the mid portion, Q. 22 slash, N; head and neck; 2/17/16. It was 22 is that proximal or distal --23 obtained at 1409 hours. Plaque in the left 23 It's in the middle. Α. 24 bifurcation slice 66 of 101. ACA open. It 24 -- or neither? Q. 25 says, fine -- fin right. Marked decrease 25 Α. It's in the middle. Page 10 Page 12 1 left MCA versus -- and then it's blank --So it's neither proximal nor 1 Q. 2 coronal. Implies left M1 mid TICI, T-I-C-I, 2 distal. It's in the middle of M1? 3 zero, slash, 41 of 101 with slight flow 3 Α. Yes. 4 distally. 4 Q. Okay. Were there occlusions 5 Okay. And TICI, the T-I-C-I, is 5 elsewhere on the CTA? 6 the method of measurement of blood flow with 6 Not that I saw. 7 7 the ideal being three? Could you tell how long the 8 Yeah. It's -- the cardiologists, 8 occlusion had been present? 9 because they deal with the myocardium, call 9 Α. No. 10 theirs TIMI. 10 Q. Is that because of this study 11 Q. TIMI. But you call it TICI? 11 itself, or is that a limitation of the CTA in 12 And we used to call it TIMI for the 12 general? 13 brain thinking it was just any artery. But, 13 Α. I'm not sure how to answer that. 14 recently, if the cardiologists could have M 14 Q. Is there something wrong with the 15 for myocardium, we could have C for cerebral. 15 question? 16 So they became TIMI, and we became no longer 16 Α. No, no, no. It's a good question, 17 TIMI, but TICI. 17 as you always have them. But I -- I'm not 18 But the point is, under the TICI sure how to -- how to answer how long it had Q. 19 scale -been there based upon that scan. 19 20 A. Same as TIMI. 20 Q. Okay. 21 -- the ideal is three? 21 Q. A. Now, I know a lot more about him 22 Α. Correct. 22 than just that scan. But just in terms of 23 Q. Zero is no flow, three is unimpeded 23 the scan by itself --24 flow? 24 Q. Right. 25 A. Correct. 25 A. -- it's -- it shows, you know, a

1 high grade lesion in the mid left M1 segment

- 2 with some flow that gets past it.
- 3 Q. How did the flow get past the
- 4 obstruction or stenosis?
- 5 A. It may be that it's not completely
- 6 occluded, although it looks that way with CT.
- 7 Q. Okay.
- 8 A. The definitive test for that would
- 9 not be CTA, but catheter angiography.
- 10 Q. Correct.
- 11 A. And so the fact that there's flow
- 12 distally could be that there's just a little
- 13 bit of flow that's very hard to see using CTA
- 14 or there is collateral flow from other
- 15 sources that provides blood flow beyond or
- 16 distal to where the obstruction is.
- 17 Q. Well, I wanted to ask you about
- 18 that. As you looked at the CTA, did you see
- 19 the presence of good collateral flow from the
- 20 meningeal arteries to the area also served by
- 21 the M1 branch of the MCA?
- 22 A. No. The -- the CTA has a very hard
- 23 time looking at collateral depending upon the
- 24 source in terms of how signal acquisition is
- 25 done.

- Page 14
- 1 Q. Well, irrespective of the
- 2 limitations of the study itself --
- 3 A. Right.
- 4 Q. -- did you see anything that you
- 5 thought to be evidence of good collateral
- 6 flow originating with the meningeal arteries
- 7 into the same territory served by the M1
- 8 branch of the MCA?
- 9 A. I did not think from that study
- 10 that there was good meningeal collateral
- 11 flow.
- 12 Q. Okay.
- 13 A. There was only distal flow. So
- 14 it's getting there somewhere. How it gets
- 15 there, I don't know. The adequacy of that,
- 16 it's not as bright as the other side.
- 17 Q. Could you tell, though, that the
- 18 flow distal to the mid point of the M1 branch
- 19 was active flow, or was it just stasis, just
- 20 blood that's apparent distal to the
- 21 obstruction?
- A. The way the study is done, it's a
- 23 time study.

24

- Q. Right.
- A. And so when you see contrast in the

- Page 15 vessels, we presume that it flowed there. It
- 2 wasn't that there had been already bright
- 3 signal seen because of clot. And we already
- 4 knew, as I mentioned earlier from the CT head
- 5 scan done that morning, that there was no
- 6 evidence of clot in the middle cerebral
- 7 artery on the CT head.
- 8 Q. Correct. Now, you mentioned two
- 9 areas of -- where you identified the presence
- 10 of calcification --
 - A. Yes.
 - Q. -- on the CT that was done that
- 13 morning?

11

12

24

- 14 A. Correct.
- 15 Q. Where were those two locations
- 16 again?
- 17 A. They're in the left vertebral
- 18 artery and the right internal carotid artery
 - 9 at the siphon.
- 20 Q. And on a traditional CT scan, is
- 21 the calcification shown by virtue of its
 - 2 greater brightness or darkness in relation to
- 23 the background?
 - A. It's bright.
- 25 Q. All right. Now, it may require you

Page 16

- 1 to look at another set of notes, but
- 2 subsequently you received a copy of an MRI
- 3 and an MRA that was performed on December 23,
- 4 2015 at University Medical Center in Lebanon,
- 5 correct?
- 6 A. Yes. But not at the time of these
- 7 notes.
- 8 Q. Oh, I understand.
- 9 A. Yeah.
- 10 Q. What I'd like you to do is tell us
- 11 what you see -- what you saw when you
- 12 reviewed the MRI and the MRA taken 12/23/15,
- 13 with particular reference to the left MCA in
- 14 Mr. Ruffino's brain.
- 15 A. The MRA is easier to discuss. The
- 16 MRI scan showed no evidence of acute ischemia
- 17 on 12/23/15 on the diffusion weighted
- 18 sequences. The inversion recovery sequences
- 19 we call flare showed prior ischemia on both
- 20 sides of the brain. The gradient sequences
- 21 showed no evidence of hemorrhage. The MRA
- done the same day as the MRI of the head --Q. On 12/23/15?
- 24 A. Correct. Showed mid M1 signal drop
- 25 out on the left with distal flow. And that

was my opinion about the outside imaging.

- Q. Okay. What do you mean by M1 2 3 signal drop out?
- 4 Well, the MRA is a very different
- 5 bit of technology than CT angiography. A CT
- 6 we give dye, and it's a lot of contrast and a
- 7 time study. With the MRA it depends upon
- 8 flow, but it has to do with how we align
- 9 protons and spin. So it's heavily dependent
- 10 upon, one, the direction of flow and the
- 11 amount of flow.
- 12 Q. Okay.
- 13 So with an MRA, when an artery is 14 narrowed to 50 percent as opposed to 60
- 15 percent or 70 percent or 80 percent, in terms
- 16 of the imaging it looks the same because it's
- 17 called time of flight imaging. So in this
- 18 particular example, it shows he's got a mid 19 left M1 segment lesion, and there seems to be
- 20 flow past it. 21 Q.
- Okay.
- 22 Α. But the degree of narrowing,
- 23 whether it's 50, 60, 70, 80, or 90 can't be
- 24 determined from that study.
- All right. Now, how were you able 25

Page 19

Page 20

- 1 Q. Okay. And with respect to the 2 magnetic resonance angiogram or MRA of 3 12/23/15, you cannot tell us to a reasonable
- 4 degree of medical certainty the degree of 5 stenosis in the M1 branch, correct?
- 6 I can tell you it's more than 50 7 percent and less than 100. But in between, I 8 can't tell vou.
- 9 Now, with respect to the MRI, you Q. 10 made reference to the presence on the flare
- 11 sequencing of prior ischemia bilaterally. I
- 12 don't know if you said symmetrically, but
- 13 bilaterally I heard?
 - Α. Yes.

14

25

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10

- 15 Q. Tell us what you were able to see
- 16 on the MRI in the flare sequence. Were they ischemic changes in the white matter alone
- symmetrically and bilateral or not? 18
- 19 They're rarely symmetric. They're
- 20 most commonly -- it's a very common finding.
- Typically, they are bilateral. They vary in 21
- 22 size. And I didn't count numbers on right
- 23 versus left. I thought the burden of change
- 24 was similar.
 - Q. Secondary to long standing

Page 18

to determine the presence of distal flow? 1

- 2 Α. Just with the scan.
- 3 Q. Okay.
- 4 Α. You look at that and you see it.
- Were you able to determine any 5
- 6 volumetric comparison with what you would
- 7 expect to be the norm for a patient of that
- 8 age, that body habitus, with his smoking
- 9 history, his hypertension, all those things,
- 10 were you able to make a comparison from a
- 11 volume standpoint of the distal flow versus 12 what you would expect to see?
- - It's difficult to do that, one.
- 14 Two, there seemed to be flow that is most
- 15 likely forward given the time of flight
- 16 signal acquisition, but the brightness of the
- 17 M2 branches seem less than the right side,
- 18 the opposite side of the brain.
- 19 So I think there was probably
- 20 sufficient narrowing that there was stenosis 21 and some limitation of flow using that
- 22 technique. You should take that with a grain
- 23 of salt though.

13

24

- Q. Stenosis means what?
- 25 Α. Narrowing.

hypertension?

- Well, we never know. The
- 3 radiologists read it secondary to all kinds
- 4 of things. But I thought they were most
- 5 likely from some sort of vascular risk factor
- in this particular gentleman.
- Specific to Ruffino, what do you
- 8 think the bilateral arguably symmetric
- 9 changes on MRI on 12/23/15 were due to?
 - Yeah. I don't think they're
- 11 symmetric. I think they're asymmetric,
- 12 number one. I suspect they're due to
- 13 smoking, age, inheritance, and
- 14 hyperlipidemia.
- 15 Q. Okay. What areas of the brain were
- 16 affected by the changes consistent with 17 chronic ischemia?
- 18 A. Only the white matter. There was
- And the cortex is the gray matter 20 Q. 21 that overlies the white?
- 22 Α. The outside of the brain, right,
- 23 where the chip set is. 24 All right. How long had the Q.

19 no evidence of cortical involvement.

25 stenosis as shown by the MRA been present?

ALFRED CALLAHAN, III, M.D. RUFFINO vs ARCHER

A. Yeah. The scan wouldn't you let
 you know that.
 Q. Based on your familiarity with this

Q. Based on your familiarity with thisform of vascular imaging and this

5 presentation among smoking Caucasian males in

6 the southeast, how long do you think it had

7 been present in this man?

8 A. For some time.

9 Q. Years?

10 A. He probably had had plaque there

11 for an extended period of time, and that may

12 be more than years, even decades.

13 Q. Okay. In your statement that you14 signed you make reference to activated15 plaque?

16 A. Yes.

17 Q. When you use the term "activated,"

18 what do you mean?

19 A. That there's been some disruption20 of the cover over the plaque and now there's

21 an interaction with circulating blood so that

22 there's debris laid on top of it.

23 Q. All right. Dr. Callahan, do you

24 have a set of notes of the imaging

25 interpretation you did on the 12/23/15

Page 21 1 phone call --

2 A. No.

3 Q. -- in August of 2017?

4 A. No. If I had, I'd have brought

5 them.

6 Q. How long was the phone call itself

7 as reflected by your invoice?

8 A. I only know that I spent roughly an

9 hour, but that wasn't the phone call. There

10 must have been something else that might have

11 been provided me.

12 Q. All right. Well, what's the

13 invoice say? Does it say phone call plus

14 review of some material?

15 A. Review of provided materials and

16 phone call three-fourths of an hour.

17 Q. Okay. Provided materials. Do you

18 have a memory of what those were?

A. No. It was my recollection that

20 the matter had been dispensed with in August

21 of 2017, so...

19

3

6

19

22 Q. In what way?

23 A. Well, I'd given my opinion and most

24 often that's that.

25 Q. How could you give your opinion

Page 22

1 studies as well?

2 A. I have a note I wrote on the

3 outside of an envelope.

4 Q. That's good enough.

5 MR. GIDEON: Let's make that the

6 next exhibit.

16

25

7 (Whereupon, the above-mentioned 8 document was marked as Exhibit No. 3 to the

9 testimony of the witness.)

10 BY MR. GIDEON:

11 Q. I want to make sure we have a

12 comprehensive oral inventory of what you have

13 and what you received. You will recall that

14 we delivered a subpoena to your office asking

15 you to have all those materials here today.

It is sufficient if you will just

17 tell us what you have and when you received

18 it. Go ahead. Start with the beginning.

19 What did you get at the outset and what did

20 you get subsequently?

21 A. Well, at the outset I had a phone

22 call. And subsequent to the phone call I

23 sent a bill, which is how I knew I'd been24 contacted in August of 2017.

Q. Do you have notes, then, of the

Page 24

about a case without having received any

2 materials?

A. Oh, I did have materials. That's

4 when I sent the invoice on the 22nd. So I

5 had to get something.

Q. We don't know what you got though.

7 A. And I don't recall either.

8 Q. And there are no notes reflecting

9 your review of the materials?

10 A. No. No. Notes are less common

11 during the month of August.

12 Q. Because you're usually in the

13 northeast?

14 A. Because I was with my

15 grandchildren.

16 Q. All right. Then you have this

17 letter that's at the end of the year 2017

18 that we've already exhibited?

A. Correct. So the letter, as I

20 mentioned, came with discs, two discs of

21 imaging. So those are the two discs that

22 came with the letter. And there's the backup

23 set of discs.

24 After that, in review there were

25 letters that I sent of invoices to

Page 25

- 1 Mr. Cummings. And then I received a
- 2 supplemental disclosure of the plaintiff's
- 3 Rule 26 and affidavit, my affidavit. And I
- 4 prepared a statement and a report. And then
- 5 I have some backup copies.
- 6 Q. That's it?
- 7 I have a list of cases. There's
- 8 supposed to be a CV. And that's it, I think.
- 9 What do you have on your computer
- 10 that you haven't printed out? For example, 11 did you get a copy of the deposition of Clark
- 12 Archer, the ER physician?
- 13 No. I haven't seen that. Α.
- 14 Q. Okay. Did you at any time get a
- 15 copy of the depositions of any of the nurses?
- Yes. I received an electronic copy 16 Α. 17 of that.
- 18 Which nurses' depositions did you Q. 19 see electronically?
- 20 Α. Well, I also got Archer
- 21 electronically, sorry. I received
- 22 electronically Archer, Ruffino, Mrs. Ruffino,
- 23 Carol McCulloch and Bromley.
- 24 Q. Any others?
- 25 Α. I'm looking. I think that's -- I

Page 27 1 Dr. Zazulia at Washington University in

- 2 St. Louis.
- 3 Do you recall seeing disclosures,
- 4 affidavits, anything else from any other
- healthcare providers?
- 6 It may be crosstalk, but I thought
- 7 I'd seen something from Duke electronically,
- but it may be a different case.
- 9 There is a neurologist in Lebanon
- 10 whose name is Deka Efobi that this individual
- 11 saw on a referral from a Dr. Luck, family
- 12 practitioner. Have you seen Dr. Efobi's
- 13 office notes?
- 14 Α. I saw a letter that he sent to
- 15 Dr. Luck in a recent email of Dr. Luck's
- 16 notes.
- 17 Q. But you have not seen Efobi's
- 18 office notes?
- 19 Α. Only the copy that he sent to
- 20 Dr. Luck with initial --
- 21 Q. For --
 - Α. -- with the initial -- his initial
- 23 consult.

22

- 24 Q. Okay. Did you ever see the
- 25 homocysteine levels for the lab tests ordered

Page 26

- think that's it. 1
- 2 When did you receive the deposition
- 3 transcripts electronically?
- 4 Α. I don't know.
- 5 Can we tell from the invoicing that
- 6 you received them before a certain date as
- 7 reflected by the bill?
- 8 The invoice I sent was on my birth
- 9 date, December 13th of '17. It only talks
- 10 about review of provided materials. But
- 11 given the length of time, that must have been
- 12 the depositions. There was a phone call and,
- 13 also, I reviewed an affidavit.
- 14 Q. Your affidavit or somebody else's?
- 15 It just says "affidavit." I
- 16 suspect that -- well, all I know is what it 17 says.
- 18 All right. Now, with the exception
- 19 of the electronic copies of the depositions
- 20 you've just mentioned, have you seen
- 21 electronic versions of any other items?
- 22 You'll recall I mentioned a Jodi Dodds,
- 23 vascular neurologist at Duke, and you said
- 24 you had some recollection of seeing something
- 25 with her name on it. You didn't recall

- by Dr. Efobi?
- 2 Α.
- 3 Q. Have you seen the entire Centennial
- 4 chart?
- 5 Α. Yes.
- 6 Q. Now, you know this patient was
- 7 transferred on the 17th from StoneCrest to
- Centennial, remained in the hospital until
- the 26th of February, and went home. Have
- 10 you seen that entire chart?
- 11 A. Yes.
- 12 Okay. All right. Before we came
- 13 here to take your deposition today, who have
- you met with with regard to the case against
- 15 StoneCrest and when did those meetings occur?
- 16 A. I met with Mr. Cummings.
- 17 When? Q.
- 18 He came last week on Thursday. And
- 19 he may have come once before, but my bills
- 20 don't reflect that.
- 21 Okay. Have you already issued a
- 22 bill for the meeting last week on Thursday?
 - A.
 - Q. How long was the meeting?
- 25 Ninety minutes. Α.

23

Q. And what was the subject matter of 2 the meeting?

- 3 Α. The deposition today.
- Are you familiar with the name of a 4 Q. physician named Trey Pope?
- 6 Pope? Α.
- 7 Q. Trey Pope, P-O-P-E?
- 8 Α.
- 9 Q. Are you familiar with the name of a 10 physician named Rajat Dhar, D-H-A-R?
- 11 Α. Yes.
- 12 Q. How so?
- 13 I'd heard about him in a phone call Α. 14 last night. And I think I had read something
- 15 that he may have written in this case,
- 16 although I may have read him in a different 17 case.
- 18 Well, did you have a phone call Q. 19 with Dr. Dhar last night or with someone 20 else?
- 21 Α. No, I'm sorry. Mr. Cummings called 22 me last night.
- 23 Q. Okay. How long was that phone call 24 last night?
- 25 Α. Half an hour.

Page 30

- Did he tell you I'd taken the 1 deposition of Dr. Dhar yesterday in
- 3 St. Louis?
- 4 Α. Yes, sir.
- 5 Q. What did he tell you about the 6 deposition?
- 7 Α. That it was complete and thorough.
- 8 Well, what did he say about the Q.
- substance as compared to the form?
- 10 Substantive testimony by Dhar?
- 11 Yeah. He reviewed with me
- 12 Dr. Dhar's opinion that because of the
- 13 location of the changes in imaging, that IV
- 14 tPA peripheral thrombolysis might have been
- 15 especially helpful. That was sort of the
- 16 main takeaway thing about it.
- Did he review with you that 17
- 18 Dr. Dhar is not a stroke neurologist?
- 19 He -- yes. He told me that at Wash
- 20 U they have a bifurcated program of care. So
- 21 they have a stroke team that lives in the ED,
- 22 and then they have an ICU team that takes
- 23 over after whatever happens in the ED. And
- 24 that Dhar is not in the ED group, he's in the
- 25 intensivist group.

Page 31

- Q. Right. But by his own admission,
- 2 did Mr. Cummings tell you Dr. Dhar said he's
- not a part of the stroke division of the
- department of neurology at Washington
- 5 University?
- 6 A. I don't know their arrangement. It
- 7 was my understanding that he's not part of
- the ED team. He's part of the intensivist
- 9 care team.

15

- 10 Q. Did Mr. Cummings tell you that
- Dr. Dhar was insisting yesterday that the 11 occlusion in M1 was very proximal --
- MR. CUMMINGS: Object to the form. 13
- 14 BY MR. GIDEON:
 - Q. -- and not distal at all?
- 16 I don't remember that. I don't
- 17 think I asked him if he knew precisely where
- 18 it was. But it was my understanding that he
- thought it was distal, and so there wasn't
- much clot in it. And, therefore, IV tPA
- 21 would have been better than I thought.
- 22 Yeah. Well, you have spent some 23 time in your career addressing the issue of
- efficacy of IV tPA alone, haven't you?
- 25 Well, my work was more catheter

Page 32 directed as opposed to the intervenous form.

- Well, back in the days when you and 2
- 3 Brian Berger were doing intra-arterial
- thrombolysis of clots, you were threading a
- catheter up to a point close to the thrombose
- and then lysing it in that fashion with
- 7 intra-arterial thrombolytic substances,
- 8 correct?
- 9 Α. Yes, that's very close. In 1994 we started doing that at Parkview Hospital. 10
- 11 Right. But in the years since
- 12 then, you have paid attention to efficacy of
- intravenous thrombolytics, haven't you? 13 14
 - Α. Yes, with what I've read.
- 15 Right. And you testified about
- 16 efficacy of intervenous thrombolytics in the
- 17 Featherston v. Mercy Health Partners case,
- 18 correct?
- 19 Α. I don't remember the names. But 20 I've had an ample opportunity to discuss the benefit that it provides. 21
- 22 Yeah. Featherston is the case 23 involving Lourdes Hospital in Paducah,
- 24 Kentucky. Do you not recall that now?
 - Α. No.

- Okay. And do you recall testifying
- 2 in Ferrion (phonetic) v. Martin Memorial
- 3 Hospital, the hospital in Martin, Florida?
- 4 Surely, you remember the name Ferrion?
- 5 No, that's harder. Is this a
- 6 recent case from Florida with Sean Domnick?
- 7 Q. Yes.
- A. 8 I remember that case.
- 9 Q. Okay. Do you recall testifying in
- 10 Featherston that intravenous tPA would be,
- 11 quote, like whistling at the incoming tide,
- 12 too much clot to lyse, end quote, in that
- 13 case?
- 14 Α. Sounds like something I would say.
- Q. 15 All right.
- Normally, I use a little science 16 Α.
- 17 with it, too, rather than colloquial
- 18 commentary.
- 19 Q. Do you recall in Featherston
- 20 testifying that tPA would have been of no
- 21 benefit in that case because tPA is only good
- 22 for about a 30 percent benefit? Do you
- 23 recall that?

1

- 24 Α. That is -- if I said that, I'm
- 25 correct because that's what the science says.

- Page 35 1 acute ischemic stroke in North America by the
- 2 FDA in June of 2016.
- 3 Correct. And that was they
- 4 permitted labelling for use up to three
- hours, correct?

6

7

- A. That is correct.
- Now, there has been a subsequent
- 8 effort to expand the permitted labelling to
- authorize the manufacturer to promote the
- 10 drug as being used for between 3 and 4.5
- 11 hours, correct?
- 12 Α. No.
- 13 Q. No. There hasn't been an effort to
- 14 convince the FDA to permit them to change the
- 15 labelling?
- 16 Α. Not that I'm aware of. Our
- 17 guidelines talk about the use of the extended
- 18 time window, but make the point that it's an
- 19 off label use of the drug.
- 20 All right. So let's just be clear
- 21 for the purposes of the record itself. Back
- 22 in February of 2016 when Mr. Ruffino was at
- 23 StoneCrest, the FDA approved labelling
- 24 allowed the use of intravenous tPA for up to
- 25 three hours after last known normal, correct?

Page 34

1

- Okay. Do you recall testifying in Ferrion same thing, that with tPA you're
- 3 wasting your time because it only has a 30
- percent benefit?
- 5 It only has a 30 percent benefit,
- 6 that statement is accurate.
- 7 Q. Okay. Thirty percent meaning what,
- 8 out of 30 out of 100 will benefit from
- 9 intravenous tPA alone?
- 10 Correct. Assuming that you
- 11 establish their candidacy like the NINDS
- 12 trial publication. That's where the 30
- 13 percent came from.
- 14 Right. NINDS is N-I-N-D-S, 1995
- 15 publication in the New England Journal of
- 16 Medicine, isn't it?
- 17 Correct. December 14th, 1995. Α.
- 18 Right. And isn't that the Q.
- 19 publication that the FDA relied upon to
- 20 permit the use of intravenous tPA for up to
- 21 three hours after the patient was last known
- 22 normal?
- 23 Α. That publication, that trial was
- 24 the basis for which the new drug approval was
- 25 granted for intravenous thrombolysis for

- Page 36 Yes. Assuming other issues of
- 2 candidacy are met.
- 3 Q. Correct. The off label use, that
- is -- has been advocated by some and
- recommended by others, is between 3 and up to
- 4.5 hours, assuming other criteria are met as
- 7 well, correct?
- 8 Α. That is correct. It's been part of
- 9 our guidelines for a long time.
- 10 Q. Right.
- 11 It's not part of the FDA approved Α.
- 12 use of Alteplase.
- 13 Now, what other articles establish
- 14 that intravenous tPA only provides benefit to
- 30 out of 100 if the patient otherwise fits
- 16 the selection criteria for use of the drug?
 - A. It's only the NINDS trial.
 - Okay. I have heard other
- 19 physicians refer to the NINDS trial as one
- 20 where it took -- you had to treat three to
- 21 benefit one. Is that accurate?
- 22 Α. It's a little bit worse than that.
- 23 but anyway.
- 24 Q. Okay. Is it your opinion in this
- 25 case then, that the probability is that if

17

- 1 Mr. Ruffino had been given intravenous tPA
- 2 alone, his probable benefit would have been
- 3 30 percent?
- 4 A. Yes.
- 5 Q. Thirty percent is less than 50
- 6 percent, isn't it?
- 7 A. Yes.
- 8 Q. Okay. In order for Mr. Ruffino to
- 9 benefit in this case, he would have required
- 10 intravenous tPA plus endovascular
- 11 intervention?
- 12 A. Yes. Or he could have had
- 13 endovascular intervention without IV tPA to
- 14 receive what I believe would be the same
- 15 benefit. The benefit between IV tPA as we've
- 16 been discussing and the benefit with
- 17 endovascular therapy are different benefits.
- 18 They're not the same.
- 19 Q. Correct.
- 20 A. Okay.
- 21 Q. Correct. But in terms of
- 22 addressing the big picture of improvement to
- 23 a more probably true than not standpoint,
- 24 more than 50 percent, Mr. Ruffino would have
- 25 required intravenous tPA plus endovascular
 - Page 38
- 1 intervention or endovascular intervention 2 alone?
- 3 A. Correct.
- 4 Q. Okay. I was surprised when I read
- 5 the Ferrion deposition. I didn't recall that
- 6 you were an attending at the city hospital.
- 7 Are you still doing that?
- 8 A. I was there yesterday in the ED
- 9 yesterday.
- 10 Q. I want to talk to you for a few11 moments about your staff privileges. You
- 11 moments about your stan privileges.
- 12 have staff privileges at Saint Thomas
- 13 currently, don't you?
- 14 A. Yes.
- 15 Q. In the department of neurology?
- 16 A. I think it's medicine. There's no
- 17 separate neuro department.
- 18 Q. How long have you had staff
- 19 privileges at Saint T?
- 20 A. Since 1981.
- 21 Q. Okay. You do not have staff
- 22 privileges any longer at Centennial, do you?
- 23 A. No, I do.
- 24 Q. You do? Are you sure?
- 25 A. Well, I think I do. I get emails

- Page 39 from them every day about getting patients
- 2 out of the hospital and paid my dues last
- 3 year. So if you know better than I, then
- 4 thanks for letting me know to get a refund.
- 5 They owe me 250 bucks.
- 6 Q. Dr. Callahan, have you performed an
- 7 endovascular procedure at Saint Thomas
- 8 hospital?

9

- A. No.
- 10 Q. Have you performed an endovascular
- 11 procedure at Centennial Medical Center since
- 12 you and Brian Berger stopped doing the
- 13 intra-arterial thrombolytic?
- 14 A. No.
- 15 Q. When did that stop?
- 16 A. About 2001. 1994 through 2001.
- 17 And we did over 400 cases.
- 18 Q. Right. Well, I particularly
- 19 remember the -- it's either a flight
- 20 attendant or a pilot with such a dramatic
- 21 improvement.
- 22 A. Yeah.
- 23 Q. Do you remember the one I'm talking
- 24 about?
- 25 A. Yeah. That one made the Discovery

Page 40

- 1 Channel. That was so big.
 - 2 Q. Yeah.
 - 3 A. But that was neither Berger nor
- 4 myself. Those were people that we had
- 5 trained during the month of August when I was
- 6 away.

- 7 Q. So you can't take credit for that?
- 8 A. Only vicariously.
- 9 Q. You haven't done any endovascular
- 10 procedures at Centennial since 2001, correct?
 - A. No, have not.
- 12 Q. What about at -- I think it's still
- 13 called General Hospital, isn't it?
- 14 A. Yeah, Metro General --
- 15 Q. Yeah --
- 16 A. -- is what they call it.
- 17 Q. Have you done any endovascular
- 18 procedures at Metro General?
- 19 A. No.
- 20 Q. When's the last time you ordered
- 21 intravenous tPA for anybody?
- 22 A. Earlier this year at Metro General.
- 23 Q. Sometime in 2018?
- 24 A. Sure.
- 25 Q. Let's just take the last two years.

1 How many times have you ordered intravenous2 tPA?

- 3 A. Probably two or three.
- 4 Q. And how many patients have you seen
- 5 in the last two years in an, you know, acute
- 6 care setting, an institutional setting?
- 7 A. I don't know the answer to that.
- 8 Q. Hundreds?
- 9 A. No. No. Because it's -- my work
- 10 at the city hospital is just four days a
- 11 month. And then it's not every month of the
- 12 year. It's 11 months most years.
- 13 Q. Would you agree that someone who 14 claims expertise in the area of stroke should
- 15 know that the outcomes utilizing intravenous
- 16 tPA alone never reach 50 percent or greater?
- 17 Don't you think somebody should know that?
- 18 A. I'd have to disagree with your --
- 19 with your question, but it's a very complex
- 20 disagreement.
- 21 Q. Well, for example --
- 22 A. And the reason is that even my
- 23 friends that know tPA is only worth 30
- 24 percent have still testified that there would
- 25 have been benefit because of post hoc

Page 42

- 1 analysis of the NINDS data. They even
- 2 published that. And I consider these men
- 3 thoughtful in their academic, you know,
- 4 bright lights and so forth. But they -- and
- 5 I understand the reason for why they say what
- 6 they do.
- 7 So it's a little more nuanced in 8 the way that you ask it. I know it's only
- 9 good for 30 percent based upon the study, the
- 10 heart science.
- 11 Q. Right.
- 12 A. And then those who were delighted 13 with the result, but disappointed with what
- 14 happened by treating physicians in America
- 15 over the next decade and a half recut the
- 15 Over the next decade and a name recut the
- 16 data to show that there was post hoc benefit,
- 17 depending on changing the definition of
- 18 benefit.
- And I felt that I know why they
- 20 wanted to say that. I shared their concern,
- 21 but I lack their enthusiasm for data dredging
- 22 and torturing the prior data. I thought the
- 23 IV tPA data was the data.
- 24 And then if you want to have
- 25 another conclusion, you have to say it's post

Page 43

- 1 hoc. We've done data dredging. We've done
- 2 all this statistical thing with propensity
- 3 matching, but you have to be very clear
- 4 channeled that you're doing it with a purpose
- 5 rather than having done a scientific study to
- 6 answer a question.
 - Q. Well, then let's distill this. The
- 8 science tells us benefit, 30 percent?
 - A. Correct.
- 10 Q. If a lawyer can read the
- 11 publications on the ESCAPE trial, the SWIFT
- 12 PRIME trial, and the EXTEND-1A trial, then a
- 13 physician ought to be able to do the same,
- 14 correct?

7

9

- 15 A. Yes.
- 16 Q. Okay. The ESCAPE, SWIFT PRIME, and
- 17 EXTEND-1A trials all demonstrate benefit of
- 18 intravenous tPA alone at less than 50
- 19 percent, don't they?
- 20 A. That is correct.
- 21 Q. Okay. Have you examined
- 22 Mr. Ruffino?
- 23 A. No

24

1

12

14

- Q. Do you think any benefit would be
- 25 served at all by you examining him?

Page 44

- A. Not for him.
- 2 Q. Do you consider your undertaking in
- 3 this case to determine his degree of function
- 4 or dysfunction? Have you been asked to do
- 5 that?
- 6 A. No, I haven't.
- 7 Q. So you're not going to be in a
- 8 position to say that he's got this degree of
- 9 permanent impairment or that degree of
- 10 disability without -- well, based on the
- 11 information you have, are you?
 - A. It would require more data.
- 13 Q. And an examination, wouldn't it?
 - A. By someone.
- 15 Q. How about you? Before you could
- 16 offer an opinion that he has some degree of
- 17 impairment or disability, that he is
- 18 permanently limited, wouldn't you have to
- 19 examine him?
- 20 A. No. Someone -- one of my
- 21 colleagues could examine him and render an
- 22 opinion that, if I read it, I would be
- 23 satisfied with what they said.
- Q. Well, have any of your colleagues
- 25 examined him, rendered an opinion, and sent

1 the materials to you for the purposes of you

- 2 forming an opinion about his degree of
- 3 impairment or disability?
- 4 Α.
- 5 Q. Have you spoken with Ruffino?
- 6 Α.
- Have you requested the opportunity 7 Q.
- 8 to do so?
- 9 No. Α.
- 10 Q. Have you ever even seen him?
- 11 Α.
- 12 Q. Did you see him on the dash cam
- 13 video?
- 14 Yes. And I listened to Glenn Beck Α.
- 15 at the same time.
- 16 Q. Yeah. From the police radio?
- 17 Α. Yes.
- 18 Q. I want to ask you about one
- 19 particular area that I think you're probably
- 20 interested in and up to speed on. I'll hand
- 21 it to you.
- 22 Dr. Callahan, have you seen this
- 23 article entitled "Acute cigarette smoke
- 24 exposure reduces clot lysis association
- 25 between altered fibrin architecture and the
 - Page 46
- 1 response to tPA"? Have you seen that 2 previously?
- 3 A. No.
- Are you aware of any scientific 4 Q.
- interest in that subject? 5
- 6 A. Not until you handed this to me.
- 7 MR. GIDEON: I'll make a copy of
- 8 this the next exhibit.
- 9 (Whereupon, the above-mentioned
- 10 document was marked as Exhibit No. 4 to the
- 11 testimony of the witness.)
- 12 BY MR. GIDEON:
- Q. Is the publication "Thrombosis 13
- 14 Research" generally regarded as reliable and
- 15 authoritative?
- A. 16 You know, I don't get this journal,
- 17 and I don't know their impact value.
- Based on your past expertise and 19 current interest in the field, do you agree
- 20 that acute cigarette smoke exposure in
- 21 smokers results in changes in fibrin
- 22 architecture and the clots associated with
- 23 those architectural changes are more
- 24 resistant to lysis with tPA than others
- 25 untreated by cigarette smoke exposure?

- Page 47
- Do you want me to read the article
- so I can respond if that's what they showed?
- 3 Q. That's what they --
 - Α. And I'm satisfied with how they
- conducted --

4

16

19

- 6 That's what they can conclude. I
- 7 don't want to spend the time to have you read
- 8 the whole article and vet it. I just wanted
- you to know whether you agreed with that
- 10 conclusion or if you have no opinion on that
- 11 point?
- 12 A. At present, I can read what they've
- written, but have no opinion on that point. 13
- 14 Q. Okay. What are the fees today?
- 15 Still \$500 an hour?
 - A. Yes.
- 17 Q. What's the charge for medical
- 18 record review?
 - Α. \$500 an hour.
- 20 Everything is \$500 an hour? Q.
- 21 Α.
- 22 Q. Is that same thing true if you
- 23 testify in person?
- 24 Α. Yes.
- 25 Q. What do you make on an annual basis

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- 1 in terms of testifying? Let's take the year
- 2 that I'm sure you just completed, and I hope
- 3 you have a memory of your Schedule C. What
- 4 did you report as additional income from
- 5 medical-legal work for 2017?
- 6 So I didn't -- I didn't tabulate
- 7 those. It's done by an accountant. I get
- little bitty things in the mail. They may be
- 9 called 1099s or --
- 10 Q. You get 1099s in the mail?
 - -- that may not be the right Α.
- 12 number.

- 13 Q. Many of them from different lawyers
- 14 and law firms?
- 15 Right. There must have been 20 --Α.
- 16 at least 20 envelopes that I opened. But
- 17 then my accountant actually adds those up and
- 18 does whatever they do with them.
- 19 Well, remember what I said earlier, 20 if you don't know the answer or you don't
- 21 understand my question, don't answer it.
- 22 Do you know what the aggregate
- 23 number was for 2017 --
- 24 A. No.
- 25 Q. -- for your medical-legal work?

ALFRED CALLAHAN, III, M.D. RUFFINO vs ARCHER

Α. Nο

1

7

11

Can you ballpark it for me? More 2 Q.

3 than X and less than Y?

4 A. No. I'm -- no.

5 Q. Is there any year in the last three

6 where you could identify that number for us?

A. I've always used the same approach.

8 The envelopes come. They open them up. They

9 add them up, and now, recently, they

10 electronically submit.

Okay. Now, you have never worked

12 as a registered nurse in any state, have you?

13 A.

14 Q. And you've never worked as an ER

15 physician in any setting, have you?

Correct. 16

17 Q. You are not expressing a standard

18 of care opinion on the emergency room nursing

19 staff, correct?

20 A. Correct.

21 Q. And you're not expressing a

22 standard of care opinion on the physician

23 extender, Mr. Rhinehart?

24 Correct. Α.

25 Or the ER physician Dr. Clark Page 49 Well, I would like to direct your 1 Q.

2 attention to just a couple of points on these

standards. If you will turn to page 3029.

4 Α. I'm there.

5 Q. And this is the area I'm looking at

(indicating). 6

7

19

3

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14

21

A. I've got it.

It makes the statement that is

9 consistent with what you just said, and that

10 is: However, because recannulization occurs

11 in only a minority of patients with large

12 vessel occlusion receiving intravenous tPA

13 alone, then it quotes 37.3 percent in the

14 ESCAPE trial. It then goes on to talk about

15 these efforts to do endovascular

16 interventional care. You've seen that

17 previously, correct?

18 A. Yes.

> Do you agree with that statement Q.

20 from this publication?

21 A. Yes.

22 Q. All right. Now, this particular

23 publication, which was released in 2015 as an

24 update of the 2013 guidelines, includes a

25 series of recommendations that then appear on

Page 50

1 Archer?

2 Α. Correct. 3 Q. Do you know Dr. William Powers

personally?

5 Α.

6 You know who he is, though, don't 7 you? He's chief of vascular neurology at the

University of North Carolina? 8

9 Α. I don't -- I don't know him.

10 Q. You are familiar with this AHA/ASA

11 guideline, aren't you? 12

Α. Yes.

13 Q. Dr. Callahan, are you a member of

14 the American Heart Association, American

15 Stroke Association?

Α. Yes.

16

17 Q. Is it one organization with two

18 names AHA/ASA?

19 That's a good question. ASA used

20 to be separate from AHA.

21 Q. Correct.

22 But I think they're probably under

23 the same umbrella. I don't --

24 Q. Okay.

25 A. I'm not really sure.

Page 52 1 page 3031. Will you turn to those, please.

2 Are you there?

A. I am.

Do you agree with me that after

release of these recommendations, the AHA/ASA

6 standards for endovascular treatment

7 established criteria that should be met

8 before a patient was considered for

9 endovascular intervention, and one of those

10 requirements was an NIHSS or NIH stroke scale

of 6 or greater, correct?

12 MR. CUMMINGS: Object to the form.

13 BY MR. GIDEON:

Q. Do you see the subsection E?

15 Yeah. So, now, these are

16 guidelines. They're not considered

17 standards. I know standards probably has a

18 particular meaning on the legal side, but for

19 us they're guidelines.

20 Q. Right.

And as part of what's gone before

22 with their meta-analysis of these trials,

23 even though not all the studies required

24 that, an NIH stroke scale score greater than

25 6 is included into E.

4

6

7

Page 53 Q. Well, tell me why, to the extent

- 2 you know, that when the AHA/ASA published its
- 3 focused update of the 2013 guidelines for the
- 4 early management of patients with acute
- 5 ischemic stroke regarding endovascular
- 6 treatment, one of the recommendations before
- 7 you would consider endovascular intervention
- 8 was, quote, NIHSS score of greater than or
- 9 equal to 6. Why was that selected?
- 10 A. I don't know.
- 11 Q. Okay. One of the other
- 12 requirements is an ASPECTS -- excuse me. One
- 13 of the other guidelines is an ASPECTS score
- 14 greater than or equal to 6, correct?
- 15 Yes. In answer to your prior
- question on page 3029. 16
- 17 Q. Yes?
- They have a whole paragraph of how 18
- 19 they came by that.
- 20 Right. Q.
- 21 A. So I don't know independently, but
- 22 they write about how they picked out six.
- 23 Okay. Did you participate in any
- 24 way in the AHA/ASA series of new
- 25 recommendations in 2015?
- Page 54
- A. No.
- 2 These guidelines remained in effect 3 through the period of time that Mr. Ruffino
- was a patient at StoneCrest and Centennial,
- 5 correct?

1

- 6 Α. Yes.
- 7 Okay. They have been recently
- updated again in the spring of 2018, haven't 8
- 9 they?
- 10 Α. They have.
- 11 Q. But the recent updates had no
- 12 application when Mr. Ruffino was a patient at
- 13 StoneCrest?
- 14 Α. That's correct. There's very
- 15 little change in the part of the guidelines
- 16 that had to do with that particular aspect of
- 17 stroke care though. They're very similar.
- 18 Have you based any of your opinions
- 19 in this case on specific published
- 20 guidelines?
- 21 Α. No. I talked about the
- 22 publications rather than the guidelines in my
- 23 affidavit.
- 24 Q. Right. And the three studies that 25 you referred to as I recall in your affidavit

- Page 55 were the ESCAPE, the SWIFT PRIME, and the
- 2 EXTEND-1A trials?
- 3 Right. EXTEND-IA. Α.
 - EXTEND-IA. Okay. Those are the
- three trials you referred to, correct?
 - - Q. Did you actually participate in any
- 8 of those three trials?
- 9 Α. I did not.
- 10 Q. All right. You agree that one of
- 11 your responsibilities as a witness offering
- opinions in this case is to offer only
- scientifically valid opinions, correct? 13
- 14 Α. Yes.
- 15 Q. You also agree that you should not
- be an advocate for or against either party? 16
- 17 A. Yes.
- Your job in this case is to offer 18
- 19 responsible scientifically valid opinion
- 20 testimony?
- 21 Α. Yes. sir.
- 22 Q. Now, can you calculate the ASPECTS
- 23 score on the CTA or the CT that were obtained
- 24 on February 17, 2016?
- 25 Α. At StoneCrest?

Page 56

- Yes. Let's start off a little Q.
- simpler. Did you do that when you looked at
- those two studies?
- 4 Α. Yes.
- 5 Okay. The Alberta Stroke Program Q.
- 6 Early CT Score is what ASPECTS stands for,
- 7 correct?

- 8 Α. Right. Canada.
 - Q. And it's focused specifically on
- 10 changes in the middle cerebral artery
- distribution, correct? 11
- 12 A. Right.
- 13 All right. When you did the Q.
- 14 evaluation of the CT in the morning and the
- 15 CTA on the afternoon of February 17, 2016,
- 16 what ASPECTS, A-S-P-E-C-T-S, score did you
- 17 assign to either or both of those studies?
 - It's done normally by radiology.
- 18 19 They actually have an algorithm that provides
- 20 the areas of interest. My review of the
- 21 record did not -- I didn't see that they had
- 22 rendered an ASPECTS score. I thought the 23 score would have been ten on both exams.
- 24 Q. Why, Dr. Callahan?
- 25 A. Because I couldn't see tissue

Page 57

change that represented acute infarction.

- Q. All right. In your opinion, does
- 3 it take six hours for the changes associated
- 4 with a stroke to appear on a CT scan?
 - A. That's the number we normally give.
- 6 Q. Is that the number you feel
- 7 comfortable with?

2

5

- 8 That's kind of a ballpark number Α. 9 that we use.
- 10 Q. Well, you were asked in the Ferrion 11 case to give an opinion to a reasonable
- 12 degree of medical certainty about how long it
- 13 would take before a stroke would appear on a
- 14 CT scan, and after some discussion, you said
- 15 six hours. Are you still comfortable with 16 that?
- 17 Oh, yeah. I'm not the only one Α. 18 comfortable with that. It's a fairly common 19 number.
- 20 Q. Okay. Well, let's talk about this 21 particular individual and when he was last
- 22 normal. What have you looked at as you've
- 23 tried to determine what was going on with
- 24 Mr. Ruffino from the night of the 16th into
- 25 the morning of the 17th in February of 2016?

 - Page 58
- 1 What data sources have you had?
- 2 Well, for that part of time only 3 the deposition testimony.
- All right. Now, did you compare 4 5 his deposition with his wife's?
- 6 No. I just read them.
- 7 Q. Well, did you notice that, to put
- it charitably, Mr. Ruffino is frequently 8
- 9 inaccurate, if not dishonest?
- 10 A. I'm not sure about his honesty or 11 accuracy.
- 12 Well, you will recall, for example,
- 13 when I began asking his wife questions she 14 pointed out that her husband had testified 15 incorrectly, to put it charitably, in a
- 16 number of ways. Did you see that?
- I recall that part of the 17 A. 18 deposition.
- 19 All right. So how much credence 20 can you give to Mr. Ruffino's deposition 21 testimony, then, given that, in terms of 22 deciding what actually happened on the
- 23 morning of the 17th of February?
- 24 MR. CUMMINGS: Object to the form. THE WITNESS: Yeah. I think it's 25

- 1 just a data point. It would be very
- 2 difficult for me in the 18th of April 2018 to
- 3 establish voracity. We rarely require that
- 4 in terms of our medical care because it's
- 5 hard to know the truth.
- 6 BY MR. GIDEON:
- 7 Okay. Well, for example, in this
- 8 case you have depositions that you normally don't have when you're treating a patient.
- 10 As a simple example, I asked Mr. Ruffino if
- 11 the neurologist, Dr. Efobi, had ever told him
- 12 to quit smoking and he said no. Dr. Efobi's
- notes document that he was instructed to quit
- 14 smoking aggressively twice. Did you see 15 that?
- 16 Α. The only copy of the neurologist
- 17 notes that I have are the letter that he sent
- 18 to Dr. Luck. And they have an item in their
- 19 electronic medical record that you have to
- 20 populate with responses, and it said to quit
- 21 smoking.
- 22 Q. Right.
- 23 A. Whether that means that he spent an
- 24 extended period of time counselling a very
- 25 heavy smoker that he needed to quit, I don't
 - Page 60
- know. The chart reflects that he indicated
- 2 in the check box that he told him to guit
- 3 smoking.

8

- 4 Q. Right. Likewise, in his deposition
- 5 Mr. Ruffino denied that he'd ever had
- 6 difficulty speaking with any prior event.
- 7 You saw that wasn't true, didn't you?
 - A. Well, he had told Dr. Luck
- different things, but anyway.
- 10 Q. Well, what I'm trying to get at --
- 11 There are differences in what
- 12 patients tell us. And I've always understood
- that was just how they communicated with me.
- 14 Well, he also testified under oath
- 15 that he first had difficulty with mini
- 16 strokes beginning in December of 2015.
- 17 Here's a copy of Dr. Luck's record. I don't
- 18 know if you've seen it or not.
 - No, I have. Because it started in
- 20 November according to Dr. Luck, and there had
- 21 been six episodes.
- 22 Okay. In fact, Dr. Luck's note
- 23 says that he was having, he being
 - Mr. Ruffino, the man who denied under oath
- 25 ever having difficulty speaking with any

6

7

10

19

25

- 1 episode, who insisted he'd never had any
- 2 symptoms in his right leg under oath, and had
- 3 insisted under oath his first trouble was in
- 4 December of 2015, on November 24, 2015 he
- 5 told Dr. Luck that he had problems right side
- 6 of face, can't talk, upper extremity right
- 7 arm, lower extremity right leg to foot, and
- 8 also that the onset began a month ago, which
- 9 would take it into October of 2015. You've
- 10 got that in front of you right now, correct?
- 11 Α. Yes. Yeah, I've seen this.
- 12 Okay. Well, given just the little
- 13 bit of time we've spent on this, wouldn't you
- 14 agree with me that Mr. Ruffino is -- give 15 that to her. We'll make that an exhibit.
- MR. GIDEON: We'll make Dr. Luck's 16 17 note the next exhibit.
- 18 (Whereupon, the above-mentioned
- 19 document was marked as Exhibit No. 5 to the
- 20 testimony of the witness.)
- 21 BY MR. GIDEON:
- 22 I'm not asking you to criticize the
- 23 man individually. But in your role in this
- 24 case, wouldn't you at least agree with me
- 25 that he is not an accurate historian and
 - Page 62
- 1 that's the most charitable thing you can say?
- 2 A. I would say it differently.
- 3 Q. Say it differently how?
- 4 Α. When the brain is involved, as it
- 5 was in this case, perhaps charity and then
- 6 some is required.
- 7 Okay. Let's take another look at 8 history. I'm going to ask you to look at the
- 9 Centennial history and physical examination 10 dated February 17th, 2016.
- MR. GIDEON: Miss, you can just go 11 12 ahead and mark Dr. Callahan's copy of that 13 and give it back to him.
- (Whereupon, the above-mentioned 14
- 15 document was marked as Exhibit No. 6 to the 16 testimony of the witness.)
- 17 BY MR. GIDEON:
- 18 Q. Have you seen this H and P from
- 19 Centennial previously, Dr. Callahan?
 - Α. Yes. sir.

20

- 21 Q. You can see from what was dictated
- 22 by this hospitalist on February 18th and
- 23 electronically signed February 21st of 2016
- 24 that this man reported dizziness, slurred
- 25 speech, facial muscle weakness, that he had

- Page 63 been having those acute events with speech
- 2 difficulty and facial weakness for the past
- month. And then in the fourth line up from
- 4 the bottom, he says, "the patient woke up
 - with the above listed symptoms."

You saw that, right?

- A. I haven't found "the patient woke
- up." I was following you, but it's in that
- paragraph, right?
 - MR. CUMMINGS: It's right there.
- 11 THE WITNESS: Near the bottom? I
- 12 got it. Yes.
- 13 BY MR. GIDEON:
- 14 Q. You see it? Now, the routine among
- 15 physicians in the field with management of
- 16 stroke is, if you wake up with these
- 17 symptoms, your last normal is when you went
- 18 to bed the night before, correct?
 - Α. Yes.
- 20 MR. CUMMINGS: Object to the form.
- 21 THE WITNESS: Yes.
- 22 BY MR. GIDEON:
- 23 Q. And what time did he go to bed on
- 24 the night of February 16th, 2016?
 - Α. It's not in this note.
- Page 64
- Just given the amount of 1 Q.
 - 2 information we've looked at so far, which is his deposition testimony, plus a note by

 - 4 Dr. Luck, and this H and P at Centennial, as
 - 5 well as your memory of the records at
 - 6 StoneCrest, when was Mr. Ruffino last normal
 - 7 on the morning of the 17th, 2016? When was
 - he last normal? 8
 - 9 Α. Well, the medical records at
 - 10 StoneCrest indicate he was normal that
 - morning after he was seen there. 11
 - 12 Right. That's one source. This
 - 13 reflects that he woke up on the morning of
 - 14 the 17th with facial muscle weakness,
 - 15 dizziness, and slurred speech. Do you know

 - 16 what time he normally arose?
 - A. No.
 - 18 Q. Do you recall from his deposition
 - 19 that he normally got up well before 6:00
 - 20 because he started working at 5:30 to 6 a.m.,
 - six days a week? 21
 - 22 I don't recall when he said in the 23 deposition that he got up.
 - 24 Okay. Bottom line then, is it may 25 well have been that he was last normal

Page 65 whenever he went to bed the night before?

2 MR. CUMMINGS: Object to the form.

3 THE WITNESS: I think he was last

4 normal a lot of times because of the nature

of what he has in terms of pathology.

BY MR. GIDEON: 6

7 Q. The current definition of a TIA is

8 what?

9 Α. Temporary neurologic dysfunction

10 lasting less than 24 hours in which imaging

is negative. 11

12 But we know that it's going to take

13 at least six hours for a stroke to appear on

14 a CT scan, correct?

15 Α. Yes.

Q. 16 How long will it take before a

17 stroke appears on an MR?

I don't think anybody knows, but 18

19 it's much quicker. Much quicker.

20 Q. Measured in hours, though, still?

21 Probably under an hour, I think, Α.

22 with diffusion weighted capability.

23 All right. Hasn't the definition

24 that you just gave us been altered?

25 There have been suggested changes I don't know of that

2 recommendation. I mean, TIAs -- the reason

we treat someone with TIA is to prevent the

stroke, not because of the TIA.

5 Q. Right.

9

6 Α. So if a patient had a TIA and has

7 clot in the neck, the treatment is removal of

the plaque in the neck.

In this particular case, though,

10 we've got an individual who has -- and I know

11 you haven't seen Dr. Efobi's entire set of

12 notes, but you have seen a letter from

13 Dr. Efobi to Dr. Luck. You have now seen,

14 again, the Luck November 24, 2015 note. We

15 know we have an individual who has had a

16 series of TIAs, correct?

17 Α. Yes.

18 Q. Is it your opinion to a reasonable

19 degree of certainty that the series of TIAs

are all originating from the stenosis shown

on the 12/23/15 MRA? 21

22 Α. Yes.

23 Q. And what is causing the events to

24 occur against the backdrop of an otherwise

25 static stenosis?

Α.

Page 66

2 Well, the definition of 24 hours

3 has been abandoned, wasn't it?

4 Generally so. Α.

5 Yeah. Why did you give me the 24

hour definition, which was abandoned in 2004?

7 A. Because it's still in our

literature. 8

1 to it.

9 Q. Okay. Well, isn't the current

10 definition, the one that was adopted in 2004

11 and did away with the 24 hour figure, one

12 that says transient neurological changes for

13 which there is no evidence of infarction?

14 Isn't that the definition?

15 A. Yes. It's become an imaging 16 requirement rather than the time plus

17 imaging. I gave you the time plus imaging.

Q. Right.

19 The truth of the matter is, the

20 TIAs don't last 24 hours. They don't even

21 last one hour.

18

22

Right. In this case, though, do

23 you -- is it normally recommended that you

attempt to do an endovascular embolectomy in

a patient that has a TIA?

Page 68 Activated plaque.

2 And what is activating the plaque

3 in each of these events?

4 Α. He must have some local disturbance

5 of flow.

1

6

9

11

18

19

23

Q. Could it be --

7 And that's probably driven by

8 platelet interactions with the plaque.

Could it be something as simple as

changes in blood pressure? 10

> Α. I don't think so.

12 Well, if we take somebody who has

13 poorly controlled and long standing chronic

14 hypertension, as you know he did, if their

15 blood pressures are diminished, is that

16 sufficient to diminish perfusion in areas of

17 significant stenosis?

Α. For critical stenosis, it can.

Okay. And you know from looking at

20 the MRA in this case that the level of

21 stenosis is between more than 50 and less

22 than 100?

Α. Correct.

24 Q. Do we know whether he had a

25 critical stenosis in the M1 branch of the

Page 69

left MCA based on the MRA?

4

16

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16

2 We know it based upon what he's 3 doing clinically.

Q. We know it's critical?

5 Α. Well, that there's activated plaque 6 and he must have periods of less flow. In

7 between, his flow must be adequate. So for

8 ten minutes he has inadequate flow, and for

9 the next hours or however long it is until

10 the next event, he has adequate flow.

Q. Okay. You testified in the Ferrion 11 12 case, Dr. Callahan, another patient that had 13 a series of TIAs, that, quote, these TIAs 14 reflect something very bad is going to happen 15 in the near term, end quote.

What is it about sequential TIAs 17 that reflects something very bad is going to 18 happen in the near term?

A. We think that TIA is a temporary manifestation of the stroke that will occur.

21 Q. All right.

22 Α. And when plaques become activated,

23 there is a window during which that stroke is 24 likely.

25 Q. What is the window?

activated plaque, so they'd had TIA or minor

2 stroke, endarterectomy was better than

medical therapy for the prevention of stroke.

This was a great step forward in medicine. 5

When that trial was published, it 6 was my expectation, not being a trialist,

7 that all the group randomized to medical

treatment immediately went and got stars

placed on their neck for surgical removal of 10 the plaques.

11 In 1998, in the New England

12 Journal, the same group that had done the

13 NASCET study of severe carotid stenosis

14 published their work for the 50 to 70

15 percent, just severe without the capital S,

16 carotid stenosis paper.

17 In that paper in the New England 18 Journal, they had a single graph of what had

happened to the individuals in the original

20 NASCET trial. And what they showed in the

21 graph is that the surgical individuals had a

22 seven percent risk of stroke at times zero

23 because there was chance of causing the

24 stroke in the operating room. And then

25 immediately after that, the graph dropped and

Page 70

It's unknown. It's probably --Α.

How do you even know there's a

3 window if the duration is unknown?

4 Do you really want me to tell you Α.

5 that?

6 Q. No.

7 I was afraid you'd say that. Α.

8 I don't want a lengthy explanation.

What I want is, how could you conceivably

10 know there is a window if the duration itself is unknown? That makes no sense to me. 11

12 Α. I'm sorry.

13 I'm just being honest with you. A Q. 14 window implies some temporal relational or a 15 spacial relationship?

I've got it. It was quite sometime 17 ago that the suggestion had been made that 18 activated plaque in the carotid would cause 19 stroke and that removal -- surgical removal 20 of that plaque would prevent stroke. That 21 suggestion was made in 1952 by Miller Fisher.

22 In 1992, published in the New 23 England Journal was the first scientific proof that angiographically proven stenosis greater than 70 percent in individuals with

Page 72

the risk of subsequent ipsilateral stroke was about one percent per year.

3 The medical group, the other part

4 of the graph, didn't go to the operating room. They still had their activated plaques

6 angiographically proven, and for the first

7 three years they were having strokes. And so

8 the line started above the seven percent.

9 And by year three, even though they had never

10 had their plaques removed or had a balloon

11 job on the plagues, they got to the one

12 percent mark. And for the next six years, to

13 1998, had a stroke rate equal to the same

14 rate of stroke of the group that had their

15 plaque surgically removed.

16 Dr. Barnett, who published these 17 two papers, had only a single paragraph in 18 the New England Journal to torture those of 19 us that like to read every page and look at 20 every graph. But here he had suggested that activated plaques in a large artery, some of 21 22 it became quiet after three years, the area 23 under the curve.

24 Because you might say, well, they 25 all had a stroke. The answer was, 25 percent

1 did. But 75 percent who never had the

- 2 operation never had an ipsilateral stroke.
- 3 And so it's just a phenomenon --
- Now I see what you mean about the 4 5 window, though. It has a temporal feature to

6 it.

- 7 So within three years for the Α. 8 carotid, if the plaque hadn't gotten you, it 9 seems like it's not going to get you. Why is
- 10 that? And Barnett never told us.
- 11 Well, do you know? Q.
- 12 We speculate, which isn't the same
- 13 as knowing, that in 1992 medical therapy for
- 14 the original NASCET trial consisted of
- 15 Aspirin, primitive blood pressure medicines
- 16 like Aldomet, blood thinners like Warfarin,
- 17 and there were no statins. That was the year
- 18 that Simvastatin, you know, first came on the
- 19 market after the publication of four S.
- 20 And Dr. Barnett never published if
- 21 these individuals in Canada and elsewhere 22 got -- now, ACE inhibitors, Lisinopril came
- 23 out that year -- got a statin, Simvastatin,
- 24 40 milligrams. Might have been given a super
- 25 Aspirin, you know, P2Y12 inhibitor like

Page 74

- 1 Clopidogrel.
- 2 I mean, the medical -- what
- 3 happened in the medical universe changed.
- 4 It's a great interest that in that same year,
- 5 1992, the plot of Americans beginning
- 6 hemodialysis with end stage renal disease hit
- 7 an inflexion point. And that inflexion point
- 8 has changed the slope.
- 9 So we theorize, though we don't
- 10 know, that medical treatment came of age.
- 11 And while some time ago you asked me about
- 12 numbers needed to treat with IV tPA, which is
- 13 12, not 3.
- 14 Q. Twelve to treat in order to benefit
- 15 one?
- 16 Yeah. For surgical endarterectomy
- 17 the numbers needed to treat are only seven.
- 18 That's a huge impact. Because of the
- 19 absolute reduction risk, not the relative
- 20 risk reduction.
- 21 So in this particular example,
- 22 there is likely to be a window in a 3
- 23 millimeter caliber blood vessel because the
- 24 middle cerebral artery stem is the same
- 25 caliber as the heart, just like we know

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- 1 there's a window in the 10 to 12 millimeter
- 2 internal carotid artery with activated
- 3 plaque.
- 4 Well, you may not know this, then,
- 5 but Dr. Efobi saw this man in December of
- 6 2015, ordered the MRI and the MRA, and then
 - saw the patient again February 11th, 2016.
- Did Dr. Efobi miss the opportunity 9 to prevent the stroke that you have said
- 10 occurred on -- sometime on February 17th,
- 11 2016?
- 12 Α. As I mentioned to you earlier, I
- 13 never -- I have only the copy of his initial
- 14 dictation.

15

19

24

13

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21

- Q. Right.
- 16 Α. There's nothing in Luck's notes
- 17 that indicate there's another visit.
- Q. 18 There are.
 - Α. But I'm not provided that.
- 20 Q. Then you can't answer the question
- 21 of whether Efobi missed the opportunity to
 - prevent the stroke?
- 23 Α. If you say I can't, then I can't.
 - Well, can you? That's my question.
- 25 Whether you have the notes or not, can you

Page 76

- 1 tell me that Dr. Efobi missed the opportunity
- 2 to prevent the stroke that you described as
- 3 occurring sometime around February 17, 2016?
- A. Yeah. Optimal medical therapy was 4
- not offered to this patient by the
- 6 neurologist at the initial visit. After
- 7 that, I don't know.
- 8 What would have been the optimal
- medical therapy to prescribe to John Ruffino
- 10 based on what is described in the thank you
- for the referral note from Efobi back to
- 12 Dr. Luck? What should have been prescribed?
 - Dual antiplatelet therapy. A.
- 14 Intensive lipid lowering.
- 15 Q. Are you finished?
 - That's all that he could have Α.
- 17 prescribed him.
 - Q. Okay.
 - He asked him to guit smoking, Α.
- 20 apparently.
 - Which he refused to do? Q.
- 22 No one ever guits smoking. Α.
- 23 But you saw he was still smoking in
- 24 the dash cam when he's waiting for the
- ambulance people to come pick him up, right?

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1

16

1 A. I saw that. I saw him take out the

- 2 cigarette and light it with his right hand.
- 3 Q. What's dual antiplatelet theory?
- 4 A. Oh, I'm sorry. Clopidogrel plus
- 5 Aspirin.
- 6 Q. And intensive lipid lowering would 7 be a statin?
- 8 A. Yes. It would require Atorvastatin
- 9 40 or 80 milligrams or Rosuvastatin 20 or 40
- 10 milligram. None of the other statins or
- 11 doses of those drugs that would be lower
- 12 would have been adequate.
- 13 Q. Okay. Do you have an opinion as to 14 the likelihood that this man would have still
- 15 had a stroke on or around February 17, 2016
- 16 if those medications had been prescribed and
- 17 if the patient had taken them after the first
- 18 visit with Dr. Efobi?
- 19 A. I don't know how long of a runway 20 you need for those drugs to have been
- 21 confident that risk would have been reduced.
- 22 Q. You cannot say to a reasonable
- 23 degree of medical certainty that it would
- 24 have prevented the stroke?
- 25 A. Correct. We have a study called

- A. Right.
- 2 Q. You're free to look at notes.
- 3 You're free to look at the images again.
- 4 Your choice. But tell us what you see.
- 5 A. I'd refer to my note, which is part
- 6 of Exhibit 2.
- 7 Q. Okay. Tell us what you see
- 8 February 18th, 2016.
- 9 A. So that study was obtained at 2018
- 10 hours at Centennial Medical Center. And it
- 11 showed restricted diffusion that was patchy
- 12 involving the deep left hemisphere and the
- 13 subinsular regions. It also showed changes
- 14 in the left temporal gyral pattern and left
- 15 high frontal gyral pattern.
 - In addition to restricted diffusion
- 17 abnormalities on DWI, the flare sequences
- 18 were positive in the same locations. The
- 19 gradient sequence showed no evidence of micro
- 20 hemorrhage.
- 21 So this -- these changes were new
- 22 that had occurred between the prior 12/23/15
- 23 MR and the MRI at Centennial.
- 24 Q. Do you agree that the MR of
- 25 February 18th, 2016 shows diffused cerebral

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- 1 SAMMPRIS that I'm sure you're aware of. And
- 2 in that study, medical treatment as I
- 3 outlined just to you proved superior to
- 4 ballooning and stenting in patients that were
- 5 having recurrent TIAs and no stroke.
- 6 Q. In this particular case, have you
- 7 had a chance to look at the MR of February
- 8 18th, 2016?
- 9 A. I have.
- 10 Q. What I would like to do now is to
- 11 switch gears and compare the 12/23/15 MRI and
- 12 the 2/18/16 MR. I know that your laptop is
- 13 equipped with the software necessary to look
- 14 at the images. You're free to look at that,
- 15 if you wish, again. Alternatively, you're
- 16 free to look at your notes. It's your
- 17 choice. But I want a comparison of the
- 18 two --
- 19 A. The study that was done before was
- 20 a CT -- I'm sorry. It's an MR.
- 21 Q. It is an MR.
- 22 A. Yeah.
- 23 Q. 12/23/15 --
- 24 A. Got you.
- 25 Q. -- and 2/18/16.

- 1 cortical loss?
- 2 A. No, I don't agree with that.
- 3 Q. You know that's in the --
- 4 A. May be in a report, but I don't
- 5 agree with that.
- 6 Q. -- dictated report by the
- 7 physician?
- 8 A. No

9

- Q. You do not agree with it?
- 10 A. No. What I thought about the scan
- 11 is what I told you.
- 12 Q. I understand.
- 13 A. It's not a full dictated report
- 14 like the radiologists do.
- 15 Q. Do you agree the February 18th,
- 16 2016 MR shows -- on diffusion imaging shows
- 17 patchy infarcts in the left basal ganglia?
 - A. That's what I just told you. I
- 19 agree with that.
- 20 Q. Okay. Do you agree that that also
- 21 shows -- that study shows embolic infarcts in
- 22 the left frontal lobe?
- 23 A. Yes. I told you that, too. High
- 24 frontal. And also left temporal.
- 25 Q. And in the left occipital lobe as

1 well?

- 2 Α. Well, that's really temporal but --
- 3 I would say temporal.
- All right. Does that make it more 4
- 5 likely than not that there was embolic
- 6 reduction of perfusion in a number of
- 7 different sites?
- 8 A. I think --
- 9 Q. Or is there -- what I'm getting at,
- 10 is there a single pathway to reduction of
- perfusion more likely than not? 11
- 12 So I think the activated plaque in
- 13 the mid portion of the M1 segment on the left 14 involved penetrating vessels to the basal
- 15 ganglia. And the stroke event was one where
- 16 there was not subsequent reperfusion in the
- 17 deep basal ganglia.
- 18 As part of the flow, no flow, flow,
- 19 no flow TIA episodes until the penultimate
- 20 one that was the stroke, there must have
- 21 distal migration of very small clots that
- 22 accounted for the change in the gyrus and the
- 23 high left frontal region and left temporal
- 24 region that you point out the reader called
- 25 the left occipital region.
- Page 82

- 1 Q. Right.
- 2 So the mechanism is activated
- 3 plaque with a local disturbance of flow of
- penetrators and distal small emboli. These
- 5 are really small emboli.
- 6 Do you --
- 7 And they had to get there because
- 8 there had to be flow that took them there.
- 9 They couldn't have gotten there with
- 10 collateral flow.
- 11 But let's make sure that we all Q.
- 12 understand what you're saying, Dr. Callahan.
- 13 Do you think there were episodes of embolic
- 14 movement here that led to inadequate
- 15 perfusion of certain areas of the brain, or
- 16 was there just one episode?
- 17 We don't know. Α.
- 18 Okay. Over what period of time
- 19 could there have been several episodes that
- 20 are consistent with what you see on the
- 21 February 18th, 2016 MR with the baseline you
- 22 have of the 12/23/15 MR?
- 23 Α. So between the 12/23/15 MR and this
- 24 MR, he had, I think, several episodes that we
- 25 know of.

- Page 83 Q. Between four to ten, depending upon
- 2 how you count them?
- 3 Yeah. I don't know how to count
- 4 because patients may have more than they
- 5 count.

6

- Q. Right.
- 7 In terms of the tissue, we know we Α.
- 8 went from no tissue damage to tissue damage.
- 9 In terms of imaging, we know we went from an
- 10 artery that had plaque that now is an artery
- 11 that seems to show that there isn't flow by
- 12 the time he gets to Centennial and they do
- 13 their studies.
- 14 As to whether the changes seen on
- 15 the MRI are all from one episode or more than
- 16 one, I don't -- I don't know the answer to
- 17 that. I know that if these changes were
- 18 there before, they weren't seen on the CT
- 19 scan at StoneCrest or seen on the CT -- part
- 20 of the CTA at StoneCrest. But we know that
- 21 that study has sort of a blind area of about
- 22 six hours.
- 23 Q. Right.
- 24 Α. This study is done the next day, in
- 25 the evening of the next day. I mean, it's

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- not done quick --1
 - 2 Q. Right.
 - 3 -- in terms of his being at
 - Centennial because he got there on the 17th.
 - 5 But we also know that CT scan
 - 6 versus the MRI have differing levels of
 - 7 sensitivity and specificity, too, don't they?
 - That's correct. We've talked about 8
 - 9 that.
 - 10 So they're not just a perfect Q.
 - 11 apples to apples comparison?
 - 12 Α. Well, they're just imaging studies.
 - 13 Correct. But they don't
 - necessarily see the same things the same way
 - 15 is what I'm getting at?
 - 16 Well, the CT will have
 - 17 perspicacity, just you have to wait a little
 - 18 bit. The MRI will see it early.
 - Q. Right.
 - 20 A. And so, in this case, by the time
 - 21 the MRI sees it, they didn't do another CT.
 - 22 He'd had the CTs at StoneCrest that didn't
 - 23 see it, didn't see it. And between CT1 and
 - 24 the CTA was, you know, four hours.
 - 25 Q. Right.

- So the fact that the first one
- 2 didn't see it doesn't mean that the next one
- 3 couldn't see it. But by 1409, it didn't see
- 4 it. As to when it happened, it's hard to
- 5 know. Because at StoneCrest, you know, he's
- 6 normal or he's not, he's normal or he's not.
- 7 Even after they call a code stroke he
- 8 continues to have what appears to be
- 9 intermittent adequate flow and then brief
- 10 periods where there's not adequate flow.
- 11 Right. It appears that he is 12 continuing to have a TIA or TIAs at
- 13 StoneCrest; isn't that right?
- 14 A. Correct. Yeah. I don't think he's
- 15 had the stroke when he gets there because
- 16 he's recorded as normal in the morning. And
- 17 when they do a code stroke, I think
- 18 Dr. Archer might have found him in the middle
- 19 of one of the episodes or in some part of the 20 episode.
- 21 And then I think in my affidavit I
- 22 go to the time point that's around 1900 hours
- 23 or sometime thereafter that no one ever
- 24 records a normal exam after that point. You
- 25 know, by then, the clinical event has
- Page 86

1 occurred.

8

23

- 2 Now, in this particular case,
- 3 though, still focusing on the MR, you have
- 4 some disagreement with the physician who
- 5 actually interpreted the study and dictated 6 the report. You don't see diffused cerebral
- 7 cortical loss on that particular MR?
 - A. Well, I didn't look at it for
- whether there was atrophy in this particular 10 individual.
- 11 Q. Well, then you might agree with
- 12 that if you looked at it again?
- It's not helpful for me thinking 13 14 about him in terms of activated plague in the
- 15 left M1 segment.
- 16 Q. You do agree that the diffusion 17 imaging shows patchy infarcts in the left 18 basal ganglia?
- 19 Α. Yes. It --
- 20 Now, when did the infarction occur
- 21 in the left basal ganglia to a reasonable 22 degree of medical certainty?
 - Α. Yeah, we don't know.
- 24 Q. Why not? Why not know?
- 25 A. Well, the perspicacity of that

- Page 87 1 image, the diffusion weighted image is two 2 weeks.
- 3 So it could have been at any time 4 two weeks prior to 2/18/16, correct?
- 5 In theory, but I don't think that's
- 6 right. And the reason is, is that that
- stroke would have been seen on the CT. And the CT at 1027 and 1409 didn't see it.
- 9 So I think in terms of imaging
- 10 there are brackets to know that that change
- 11 is going to be when he has now clinical
- 12 events just like he's always had, but now
- 13 they persist. 14
 - Q. All right.
- 15 And we don't know exactly when that Α.
- 16 happened. But it's clear that by 1927 or so
- he's no longer having an exam where people 18 say, well, he's normal to me now.
- 19
- Q. However, in terms of putting the
- 20 parameters on the timeframe, we know what's
- 21 apparent on February 18th, 2016 in the
- 22 evening when the MR is done. We also know
- 23 the CT scan is sensitive to identify the
- 24 changes up to six hours before the imaging.
- 25 So we know in this case that it goes back to

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- 1 two hours before the original CT, if we use 2 the CTA as the most sensitive up to the time
- 3 of the MR?
- 4 A. Well, now your question presumes
- 5 that he could have the basal ganglia stroke,
- 6 but be asymptomatic, that that just happens
- 7 to be an incidental thing. And I don't know
- 8 that that's the case.
- 9 Well, what would be symptomatic of
- 10 a permanent injury in the left basal ganglia?
- 11 A. Yeah. I would expect that if it's
- 12 big enough he would have weakness involving
- 13 the right face and right arm, with or without
- involvement of the right leg. And that the
- 15 speech would be thick. But, again, it has to
- 16 be big enough.
- 17 But we know he has had repeated 18 episodes of weakness in the right face, thick
 - speech. We just don't know how long they've
- 20 lasted, do we? 21 Well, I think Valdivia said they Α.
- 22 were stereotypic episodes. They're all the
- 23 same. And he pegged them between 10 and 14
- 24 minutes, if that can be relied upon.
 - Well, how long does it require for

ALFRED CALLAHAN, III, M.D. RUFFINO vs ARCHER

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1 us to have inadequate perfusion in the basal

- 2 ganglia before there is permanent injury to
- 3 the tissue? How many minutes of inadequate
- 4 perfusion?
- 5 A. Yeah. I don't know the answer to
- 6 that.
- 7 Q. You couldn't because it's a
- 8 function, isn't it, of how inadequate the
- 9 perfusion is for how long?
- 10 A. And there are more variables than
- 11 that.
- 12 Q. As well as the metabolic demand of
- 13 the tissue?
- 14 A. And more variables than that.
- 15 Q. Right. The bottom line is, it's an
- 16 unknowable answer, isn't it?
- 17 A. Correct.
- 18 Q. Okay. Likewise, you agree that
- 19 there are embolic infarcts in the left
- 20 frontal lobe. When did those occur?
- 21 A. Yeah, I don't know when.
- 22 Q. And whether it's the left temporal
- 23 lobe or left frontal lobe, left occipital
- 24 lobe, whatever the point, you don't know when
- 25 those occurred either, do you?

Q. Can you do that?

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- A. It would be difficult because it's
- 3 patchy. I know how to do that, but I didn't
- 4 attempt to do that measure.
- 5 Q. Now, did you do an ASPECTS score on 6 this particular study?
 - A. I don't do ASPECTS on MRs, only CT.
- 8 Q. How about the size of the penumbra
- 9 on the MR February 18th, 2016, could you make
- 10 an assessment of the impaired, but not
- 11 infarcted tissue?
- 12 A. No. The CT perfusion study did
- 13 that, which was done earlier in the day on
- 14 the 18th at Centennial.
- 15 Q. Right. Well, we'll turn to that
- 16 right now. There's another perfusion scan
- 17 February 18th, 2016. Have you had a chance
- 18 to actually look at that yourself?
 - A. Yes. That was done at 1247 hours.
- 20 Q. What was the size of the penumbra?
- 21 A. The area of diminished perfusion is
- 22 quite large and looks like all of the middle
- 23 cerebral artery territory on the left.
- 24 Q. Okay. Compare that with the
- 25 ischemic core?

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- 1 A. No. But I'm -- I'm very
- 2 parsimonious in thinking, and given that the
- 3 DWI is positive and so is flare, I think all
- 4 of these things run together rather than
- 5 saying, there was a little one that went to
- $6 \hspace{0.1in}$ the left temporal lobe, and then some unknown
- 7 delta passes and goes to the high left
- 8 frontal lobe and then there's another delta
- 9 time and now we've got patchy change in the 10 DWI.
- 11 Clinically, I think that he has an
- 12 event at StoneCrest for which that's the
- 13 stroke. And the imaging that they have at
- 14 Centennial on the next day evening makes it
- 15 look like that's the stroke. That fits very
- 16 nicely.
- 17 Q. What's the size of the infarct as
- 18 shown on the MR of February 18th? How big is
- 19 it?
- 20 A. I don't know the volume. And
- 21 neither did the reader provide a volumetric
- 22 measure.
- 23 Q. Right. Were you able to measure
- 24 the size of the infarct core lesion yourself?
- 25 A. I did not attempt.

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- A. It's much smaller. So there's a
- 2 diffusion perfusion mismatch. Those are the
- 3 cases we look for because we can intervene by
- 4 providing flow and hit home runs rather than
- 5 bunts.
- 6 Q. Right. So when you have a mismatch
- 7 with the ischemic core and a large penumbra,
- 8 that's one of the things where it's an
- 9 opportunity to intervene, right?
- 10 A. Where we should go to the cath lab.
 - Q. Right. You don't cease that
- 12 opportunity by giving the patient intravenous
- 13 tPA, though?
- 14 A. Well, it's allowed that you could
- 15 give them tPA, but you need to be headed to
- 16 cath lab while you're infusing the drug.
- 17 Q. Okay.
- 18 A. But these are the cases that -- the
- 19 large vessel occlusions that we live for. I
- 20 mean, all the systems have to primed to -- on
- 21 the lookout for these cases to want to do
- 22 these.
- 23 Q. Well, was there still an occlusion
- 24 as of the time the perfusion scan was run?
- 25 A. It doesn't give you any data about

- 1 that, only that flow is diminished. So you
- 2 presume that the activated plaque must still
- 3 be activated. As to how much flow might be
- 4 there, I don't know the thresholds for how
- 5 they set their device to calculate how much
- 6 residual flow could be present.
- 7 Q. Well, I want to make sure that
- 8 we're communicating. Isn't it true that the
- 9 perfusion scan does not identify any complete 10 occlusion?
- 11 A. I don't know how it could identify
- 12 a complete occlusion. It's just perfusion.
- 13 So there's reduced perfusion throughout the14 left MCA, and read by Dr. Lassiter.
- 15 Q. Right. Do you know Dr. Lassiter?
- 16 A. Very well.
- 17 Q. He's a very talented, capable guy,
- 18 isn't he?
- 19 A. He is that.
- 20 MR. GIDEON: Mark this, please.
- 21 (Whereupon, the above-mentioned
- 22 document was marked as Exhibit No. 7 to the
- 23 testimony of the witness.)
- 24 BY MR. GIDEON:
- 25 Q. What I'm interested in is the

- Page 95 perfusion, then he describes the areas. Then
- 2 he goes on to say, "without evidence of
- 3 ischemia at this time."
- 4 What had relieved the occlusion by
- the time the perfusion scan was done at
- 6 Centennial on the 18th at noon?
 - A. Do you mean, how did it happen?
- 8 Q. Yeah.

7

- 9 A. Well, assuming that his study means
- 10 that there's now TICI 3 flow, which I don't
- 11 believe it does, but that's something to ask
- 12 him rather than myself. We know that with
- 12 min rather than mysen. We know that with
- 13 activated plaque there can be spontaneous
- 14 flow again, and maybe that happened.
- 15 Q. Well, what I'm asking you to do is16 take your background and your experience, and
- 17 as you look at the report and you also have
- 18 the benefit of having looked at the perfusion
- 19 scan images themselves, was there evidence of
- 20 ischemia at the time of the perfusion scan to
- 21 your eyes?
- 22 A. It's only a perfusion study for me,
- 23 not an ischemia test.
- 24 Q. Okay. You're not in a position,
- 25 then, to disagree with his conclusion that

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- 1 report by this talented, capable individual2 we both know.
- 3 In his findings he says,
- 4 Dr. Callahan, "There is deceased mean transit
- 5 time and time to peak throughout the left
- 6 middle cerebral artery distribution." Point
- 7 here being, that is the technique used to
- 8 identify the penumbral tissue, correct?
- 9 A. Right.
- 10 Q. All right. And that penumbral
- 11 tissue is in the perisylvian left frontal,
- 12 temporal and parietal lobes, correct?
- 13 A. That's what he wrote.
- 14 Q. Okay. Then he says, "There is
- 15 relatively normal cerebral blood flow and16 cerebral blood volume."
- Was there, in fact, an occlusion in the left MCA M1 branch at the time this perfusion scan was done?
- 20 A. Yeah. He doesn't know.
- 21 Q. Do you, from looking at it 22 yourself?
- A. No. No. But that would be a good question for you to ask Dr. Lassiter.
- 25 Q. His impression is decreased

- Page 96 there was no evidence of ischemia at the time
- the study occurred?
 - A. No.
- 4 Q. Okay. Similarly, is one potential
- 5 explanation for the absence of ischemia that
- 6 the occlusion had been lysed in some fashion
- 7 on its own?
- 8 A. Well, against that theory is what
- 9 we learn with the MRI later that evening. So
- 10 maybe he was flowing at this instant, which I
- 11 don't believe. And I don't believe
- 12 Lassiter's report really means that, if you
- 13 ask him, as compared to that it's still
- 14 occluded.
- 15 Q. Well, what would explain it if, in 16 fact, that is his point?
- 17 A. You should ask him so he could 18 explain it.
- 19 Q. All right. But what was the
- 20 point --
- 21 A. Because I can't explain what he's 22 trying to tell you.
- 23 Q. Okay. You have had access to the
- 24 entire Centennial record, and there are
- 25 several notes here by people you know. I'll

Page 97

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Page 98

give you a copy of Ron Wilson's note of February 20th. 2

3 MR. GIDEON: We'll make this the 4 next exhibit.

5 (Whereupon, the above-mentioned 6 document was marked as Exhibit No. 8 to the

7 testimony of the witness.)

BY MR. GIDEON: 8

9 And I'm not going to force you to 10 race through the note, but if I'll look to 11 the third page, you'll see this is a note 12 that was electronically signed by Ron Wilson

13 at 11:00 on February 20th, 2016. 14 In that, at the top in the free

15 text assessment and plan he states, "Problem 16 number one, complex left middle cerebral 17 artery hypoperfusion syndrome due to partial 18 occlusion of MCA vessels."

19 Now, is there anything on the 20 imaging up to and including the 20th that 21 supports the conclusion that there was 22 partial occlusion of the MCA vessels?

23 Α.

24 Q. Is there anything about the 25 clinical findings up to and including

Q. Yeah. How would you otherwise go 2 from a 13 to 3, assuming both are accurately calculated, unless there has been restoration of perfusion?

5 Α. You know, I'm a flow guy. But the 6 other -- my other stroke colleagues think that there can be other things that go on having to do with excitotoxicity, various 9 somatic things that happen.

> Q. What do you think?

11 This particular man got Α.

12 Minocycline, which is thought to maybe

provide some sort of benefit in terms of neuro resuscitation. But I'm -- but I'm

still a flow guy. So I think there must have been some way to get augmented flow. 16

> How did that happen? Q.

18 Α. Only God knows.

19 Q. If we presume that a flow guy is

20 right, how did flow get restored in this case

21 so as to improve the NIH stroke scale from 13 22 to 3 without endovascular intervention and

23 without intra-arterial or intravenous tPA?

24 How did that happen in this particular case? 25

Α. Yeah. I don't know.

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1 February 20th that support Dr. Wilson's 2 statement that there is a partial occlusion

3 of the MCA vessels?

Yeah. I would have said it 4 Α. 5 differently. He records the stroke scale 6 score of 3.

7 Q. Correct.

8 Α. On admission, the stroke scale 9 score was 13. And so his presumption is that

10 the patient has gotten better because there's

11 been restoration of flow. And I hate to

12 speak for him, but that would be what I would

13 imagine he was thinking.

Q. Okay.

14

15 He didn't articulate because of the Α. 16 NIH stroke scale score going from 13 to 3, 17 with the above mentioned imaging, this is my 18 opinion. He just simply wrote that is --

19 what he wrote. This is what he's typing.

20 Right. Dr. Callahan, for a person 21 to be accurately 13 on the NIH stroke scale 22 and then for it to be 3 48 hours later,

23 doesn't there have to be intervening

24 perfusion?

25 By some means, I would think.

Q. All right. What's the exhibit number on Dr. Wilson's note?

I think it's 9.

THE COURT REPORTER: It's 8.

BY MR. GIDEON: 5

6 You will recall from looking at the 7 record that Dr. Valdivia's plan of care was to permit permissive hypertension, to keep the patient in bed frequently with the head down. And it worked pretty well, didn't it? 10

11 Well, that's what he did. Whether 12 it's the reason that things changed or not, I've always been skeptical of the blood 13 14 pressure guys.

15

Okay. It's a school of thought Q. that you have some skepticism about? 16

> A. Yes.

18 Q. I'm not trying to turn this into a 19 personal comparison --

A. No, no, no, no.

21 -- between you and Dr. Valdivia, Q.

but is it a school of thought difference that 23 you have some skepticism about permissive

24 hypertension?

> Α. I have some skepticism about it.

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1 Q. All right. Well, then,

2 fundamentally?

A. And the reason is that patients canget better and it doesn't have anything to dowith what we did.

6 Q. Well, is that what happened here, 7 in your opinion?

8 A. He may have gotten better because
9 of part what they did do in terms of Aspirin
10 and Clopidogrel and maybe some of the other
11 medical treatments made a difference. We

12 don't know.

13 Q. To a reasonable degree of medical 14 certainty then, you can't say even with the 15 benefit of hindsight why Mr. Ruffino 16 improved, correct?

17 A. Correct.

18 Q. All right. He discharged on 19 February 26 for the first occasion.

20 MR. GIDEON: This is Dr. Valdivia's 21 note of February 26.

22 (Whereupon, the above-mentioned 23 document was marked as Exhibit No. 9 to the 24 testimony of the witness.)

THE WITNESS: This is the discharge

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1 dressing himself, doing all those things.

2 Did you not see that when you looked at the3 chart yourself?

4 A. I don't recall that part. I recall

5 seeing an NIH stroke scale score of 6, which6 is why I was keen to know if you had had the

7 other sheets.

Q. I don't. Why did this man get to
the point where he's able to speak normally,
able to walk, able to dress himself, able to

11 eat and walk out of the hospital on the 26th,

to a reasonable degree of medical certainty?MR. CUMMINGS: Object to the form.

14 THE WITNESS: Because he only had a

15 small stroke rather than a big stroke.

16 BY MR. GIDEON:

17 Q. Okay. What assurance does he have
18 as he walks out on the 26th that he's not
19 going to have a recurrence of TIAs or another
20 big stroke?

21 A. He has no assurance.

Q. What's the probability as this man walks out of the hospital on the 26th that he will have a large stroke at sometime in the

25 future?

1

9

11

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1 note?

25

3

2 BY MR. GIDEON:

Q. Yeah. This is the note by

4 Dr. Valdivia on the 26th.

A. And do you have his NIH stroke
scale number? Because it says one of four,
so there's more to the note than what you've
given me.

9 Q. Well, I don't. You've got the 10 chart. You're free to look at it, if you 11 wish.

12 A. I only have an electronic version 13 of the chart, so...

Q. Okay. Well, I don't have the NIH
stroke scale with me. The individual is
ambulating on his own. He's able to speak,
able to dress himself, able to eat, able to
do all these things. What --

19 A. Well, it doesn't say those things, 20 but --

Q. I know from looking at the rest of
the chart that he was able to do that on the
26th. He walked out of the hospital, was

24 able to talk to people. He was going up and

25 down the hallways, eating normal food,

A. It's very good.

2 Q. Meaning what? Put a number on it.

3 A. More likely than not.

4 Q. Okay. Why?

5 A. Because they hadn't fixed the6 problem.

7 Q. And what would you have to do to 8 fix the problem?

A. Eliminate the activated plaque.

10 Q. How do you do that?

You'd have to use the cath lab.

12 Q. And would you take the activated

13 plaque out of the vessel?

14 A. No, not in the MCA. Typically, at
15 this institution in the old days it was done
16 by balloon angioplasty without placement of a
17 stent.

18 Q. So in order to minimize the more 19 probable than not likelihood of a future

20 major stroke, this man needed to have a PTCA?

21 A. That's what I would have 22 recommended for him.

23 Q. And given the fact that it's 2016

24 instead of 2018, would it have been limited

25 to a PTCA or would a stent have been placed?

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- Well, in the old days in another
- 2 century at that institution, more than 120
- patients were treated and only one ever had a
- 4 stent placed. And that stent was placed in
- 5 the vertebral basilar artery system in order
- 6 for rescue. And there was a paper published
- 7 about 127 patients in that series by Berger
- 8 and myself, as well as the endovascular
- 9 rescue with stent placement because it was
- 10 the first placement of an endoprosthesis
- 11 intracranially in the world.
- 12 Okay. But what about this man,
- 13 what would have been done, stent or PTCA
- 14 alone?
- Just balloon angioplasty and 15 Α.
- 16 medicines.
- 17 Q. Why hasn't he had a major stroke
- 18 since then?
- He did have another stroke. 19 Α.
- 20 Q. But he went home?
- 21 Α. Came back again with more trouble.
- 22 Q. Right.
- 23 Α. And a much higher NIH stroke scale 24 score.
- 25 Q. He went home and he fell down in

- 1 following the event?
 - A. In what year?
- 3 2016, February of 2016.
 - In that year and in that artery it
- was six hours, although some of the trialists
- went out to eight.
 - But no more than eight?
- 8 Yes, no more than eight.
 - All right. The trials usually
- 10 attempt to measure outcomes based on death at
- some point in time, incidents of intracranial
- 12 hemorrhage, and a measurement of function,
- 13 frequently the Modified Rankin Score of the
- goal being between zero and two, correct?
 - A. I would have said it differently.
- 16 But the outcomes are prescribed for the trial
- before the trial is conducted.
- 18 Q. Correct.
 - Α. And the benefit in the more recent
- 20 studies is a Modified Rankin Score at 90 days
- 21 between zero to two.
- 22 Okay. That's what I'm getting at.
- 23 Modified Rankin Score between zero and two is
- 24 a measurement of functional independence,
- 25 isn't it?

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- 1 the bathroom, according to him. Did you see
- 2 his history about that?
- 3 Α. Yes.
- 4 Q. He then got progressively worse and
- 5 waited 15 hours before he came back to the
- 6 hospital. Wasn't it a failure to act
- 7 reasonably on his own part to wait 15 hours

We think patients need to come

- 8 before returning to the ER?
- 10 quickly to help.

Α.

9

- Well, answer the question, then, 11
- 12 Dr. Callahan. In order to exercise
- 13 reasonable care for his own health, safety,
- 14 and welfare, shouldn't he have returned to
- 15 the hospital much sooner than 15 hours after
- 16 the index event?
- 17 Α. Sure. He should have come
- 18 immediately back to care.
- 19 Okay. And if he had done so, would 20 there have been the opportunity to perform a
- 21 PTCA and either place a stent or elect not to
- 22 place a stent?
- 23 Α. There might have been.
- 24 Okay. What is the timeframe within Q.
- 25 which percutaneous intervention may occur

- Α. Yes.
- 2 Q. It doesn't mean that you don't have
- 3 any limitations, right?
- 4 It would if you had a score of Α.
- 5 zero.
- 6 Q. Correct.
- 7 But the definition of benefit is
- 8 those with zero and those with one and those
- 9 with two.
- 10 Okay. What is the level of
- 11 functional independence with a Modified
- 12 Rankin Score of one? What is it that's
- 13 limited, impaired, or disabled?
- 14 Yeah. They have -- they have some
- 15 disturbance of function and they can't use a
- walker. 16

17

- Q. Cannot use the walker?
- 18 Α. Yeah. I mean --
 - Q. They're in a wheelchair?
- 20 Α. Yeah -- no, no, no. They don't
- need a walker or anything like that. 21
- 22 Q. Don't need a crutch?
- 23 Α. I think they can have a stick.
- 24 They can't use the walker.
- 25 Q. Okay.

1 A. And for a two, they can use a

- 2 walker, but it cannot have wheels.
- 3 Q. Okay. Do you know if Mr. Ruffino
- 4 is able to ambulate without assistance?
- 5 A. I don't know the answer to that.
- 6 Q. If he is able to ambulate without
- 7 assistance, able to communicate, able to
- 8 dress himself, does he have a Modified Rankin
- 9 Score of one or two?
- 10 A. I'd have to see him.
- 11 Q. You would?
- A. And probably somebody that has seen
- 13 him might have used those scales.
- 14 Q. What about incompetence of speech,
- 15 some people refer to it as dysarthria?
- 16 A. We call that thickness of speech.
- 17 Q. Yeah. If we use the term
- 18 "thickness of speech," and that is the only
- 19 limitation, where does that fall on the
- 20 Modified Rankin Score?
- 21 A. I presume by that you mean that he
- 22 has no aphasia.
- 23 Q. Right.
- 24 A. So it's just his speech is thick.
- 25 He can think and remember, knows what things

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1 might have done that as part of his exit note

- 2 or it might be in the discharge summary,
- 3 since they're contemporaneous and know how
- 4 he's doing things. And that's why I wanted
- 5 to know what they said. I would be unable to
- 6 come up with a number with what you've shown
- 7 me here. And I'm sure that must be somewhere
- 8 in the record.
- 9 Q. Okay. I want to talk to you about
- 10 the ESCAPE trial. The full name of the study
- 11 was the "Endovascular treatment for Small
- 12 Core and Anterior circulation Proximal
- 13 occlusion with Emphasis on minimizing CT to
- 14 recanalization times," fortunately called
- 15 ESCAPE.

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- 16 A. Its' ESCAPE IA.
 - Q. Do you recall that it required an
- 18 NIHSS of greater than five to be included in
- 19 that study?
- 20 A. No. I would look at the New
- 21 England Journal article again. But since you
- 22 probably have it before you, I'm confident
- 23 with your report.
- 24 Q. It also required to be included
- 25 moderate to good collateral circulation

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- 1 are, can name those things, can write, can 2 read, it's just simply he has dysarthria.
- 2 read, it's just simply he has dysarthria.3 Q. And is not articulate, somewhat
- 4 slow, where does that fall on the MR -- the
- 5 Modified Rankin Scale?
- 6 A. And that he's able to chew and
- 7 swallow without impairment?
- 8 Q. Yeah.

18

- 9 A. Yeah. That would be a one.
- 10 Q. What about limited handwriting
- 11 skill on the ipsilateral side and --
- 12 A. Contralateral?
- 13 Q. Contralateral side, yes. Limited
- 14 handwriting ability on the contralateral side
- 15 and some thickness of speech together, is
- 16 that a Modified Rankin Score of two, but
- 17 otherwise able to ambulate?
 - A. Yeah. It's going to be close to
- 19 two. You know, we actually -- it's been
- 20 modified subsequently so there can be 1.5s as 21 opposed to 1s.
- 22 Q. Well, where would you assess him on
- 23 the Modified Rankin Scale when he left
- 24 Centennial on February 26th?
- 25 A. I was hopeful that Dr. Valdivia

Page 112 defined as filling 50 percent or more of the

- 2 middle cerebral artery pial arterial
- 3 circulation, correct?
- 4 A. Again, I trust you with the
- 5 recitation.
- 6 Q. In your opinion, did this man have
- 7 on any of the imaging studies you saw 50
- 8 percent or more of the MCA artery pial
- 9 arterial circulation supported by good
- 10 collateral circulation?
 - A. I'd ask the imagers that question.
- 12 Q. You don't know and don't have an
- 13 opinion?

- 14 A. No, because they didn't conduct the
- 15 studies that they did in ESCAPE to arrive at
- 16 that.
- 17 Q. Okay. In that study, the mortality
- 18 at 90 days was 10.4 percent in the
- 19 intervention group. What were the principal
- 20 causes of death among those patients placed
- 21 in the endovascular intervention?
- A. I'd have to look at the article to tell you.
- 24 Q. Okay. Do you recall that the
- 25 lowest NIHSS for endovascular intervention

1 was 13? Among all the patients actually

- 2 included the lowest was 13?
- No. They wanted, you know, severe
- 4 strokes. And, typically, that's somewhere
- 5 north of 10 that we start thinking about the
- 6 NIH stroke scale score as a surrogate for
- 7 severity. And they probably excluded ones
- 8 above 25 because those are too severe.
- 9 Q. With respect to the control group,
- 10 which is shown on table 1, the lowest NIH
- 11 stroke scale was 12. Did you know that?
- 12 No. But they want to have a
- 13 homogenous group because they randomize these
- 14 individuals.
- 15 Q. Okay. Turning to SWIFT PRIME,
- 16 which is another study you brought up, the
- 17 "Solitaire FR with the Intention for
- 18 Thrombectomy as Primary Endovascular
- 19 Treatment of Acute Ischemic Stroke," SWIFT
- 20 PRIME. The NIH stroke scores range from 8 to
- 21 29 in that study. Did you recall that?
- A. No. But I'm delighted that they 22
- 23 included people up to 29.
- 24 Q. The -- you will recall that this
- 25 was one the studies that had a particular

Page 115 tissue volume for infarction than the rapid 2 software.

- 3 Q. Okay. Now, in this particular
- study of those that were randomized to just
- 5 intravenous tPA alone, the -- that group of
- people that got to the Modified Rankin Score
- 7 of zero to 2, only 35 percent of those. Do
- 8 you recall that? 9
 - Α. I trust you.
 - Q. Okay. And then, last, the
- "Extending the Time for Thrombolysis in 11
 - **Emergency Neurological Deficits**
- Intra-Arterial," also known as EXTEND-1A? 13
 - Α.
- 15 Q. IA. They split the participants
- 16 between intravenous tPA only or IV tPA and
 - endovascular therapy with a stent retriever,
- 18 correct?

10

14

19

- A. Yes.
- 20 A mismatch ratio of greater than
- 21 1.2 required in this case and an absolute
- 22 mismatch volume of greater than 10
- 23 milliliters, an infarct core lesion of less
- 24 than 70 milliliters as assessed by the rapid
- 25 software. Do you recall what the results

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- 1 target mismatch profile that was required,
- 2 correct?
- 3 A. It required, actually, rapid
- 4 software, which had been developed at
- Stanford and was only available at certain 5
- 6 select centers.
- 7 Correct. Using that special
- 8 software, they had to have an ischemic core
- 9 lesion that was not greater than 50
- 10 milliliters, no more than 100 milliliters of
- 11 tissue, with time to maximum delay of greater
- 12 than 10 seconds and a mismatch ratio that
- 13 exceeded 1.8, correct?
- 14 Α. I trust you with your recitation.
- 15 What was the size of the ischemic Q. 16 core lesion in Mr. Ruffino?
- 17 It was not measured by any of the 18 contemporary radiologists, neither was it
- 19 calculated by me. As we spoke before, those
- 20 calculations that could have been made by me
- are not the same as the rapid numbers that 21 22 you mentioned in that trial.
- 23 Typically, the rapid numbers, the
- 24 ABC/2 rule, which is what we use, generates
- 25 numbers that are a little lower in terms of

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- were in that study for those that got IV tPA 2 alone?
- 3 Α. I'm sure you'll tell me, but it
 - exceeded 50 percent.
- 5 No. It was less than 50 percent. IV tPA alone on 37 percent.
- 7 I'm sorry. For endovascular
- 8 exceeded 50 percent. I don't know the IV tPA 9
 - number.
- 10 Q. Okay. Is there anything else
- 11 that's underway right now, any other trial
- 12 underway right now, Dr. Callahan, that
- 13 compares to ESCAPE, SWIFT PRIME, or
- 14 EXTEND-IA?
- 15 Well, there are a number of ongoing Α. 16 studies for acute stroke.
- 17 Any expected to be releasing their 18 results shortly before our trial in January?
- 19 Α. The MR CLEAN boys are busy trying
- 20 to see if IV tPA is necessary. Q. With endovascular care?
- 22 That rather than being at a center
- 23 that can't do the cath lab and then staying
- there to get IV tPA before you go to the cath
- 25 lab, if that's a reasonable program. But

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4

- 1 the -- that study, I don't know where they
- 2 are with enrollment or when they plan to
- 3 report out. They did not report out at the
- 4 recent stroke meeting in LA in February.
 - Q. Okay.
- 6 Α. And there was really not much talk
- about it, and there shouldn't have been much 7
- talk about it. 8

5

- 9 Q. All right.
- 10 A. But that's going to be the next.
- 11 The next horizon, then, is whether
- 12 to eliminate use of intravenous tPA and just
- 13 proceed directly to endovascular
- 14 intervention?
- 15 Yes. And -- and the issue that's Α.
- 16 implicit in that is, how do you figure out in
- 17 the periphery that it's large vessel
- 18 occlusion so they need to go quickly to the
- 19 cath lab somewhere else or they should get IV
- 20 tPA because it's not a large vessel. And in
- 21 Holland, they may have an easier way to do
- 22 that because the country is so small.
- 23 But in America, that's going to be
- 24 the issue with whatever they tell us,
- 25 whatever they've learned scientifically, what

- phenomenal. Just because of the difference
- in the technology. And I think that's why
- it's become so good.
 - But they haven't learned how to
- rescue all of those patients. It doesn't
- always work. And there's issue with, you get
- 7 reperfusion, so TICI 2B or 3, but yet
- something happened in the microcirculation.
- And for that, there still may be a place for
- 10 the administration of lytic therapy for the
- 11 smaller clots that are still there in the
- 12 microcirculation.
- 13 So while it is true in the
- 14 guidelines, they seemingly are irreverent of
- 15 the old guys that did work in the last
 - century with catheters, of which I'm one
- 17 speaking to you. There may be something
- 18 about our technique that will be useful even
- 19 for the new jet flyers.
- 20 Well, the reason I ask that is that
- 21 there is a specific statement in the 2015
- 22 guidelines that emphasizes that
- 23 intra-arterial use of thrombolytics is not
- 24 approved by the FDA, and it doesn't spend any
- 25 time talking about when that option should be

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5

- 1 does that mean for how we're going to care
- for people in a massively sized country where
- 3 endovascular capability is only in certain,
- you know, centers.
- 5 Q. Currently, tPA is not approved by
- the FDA for intra-arterial use, correct?
- 7 A. That's correct.
- 8 Has the intra-arterial
- administration of tPA been pushed by the
- 10 wayside? Been there, done that, is that
- 11 the --
- 12 Well, it was never tPA. The
- 13 studies were done without tPA, was done with
- 14 an agent that never made it to FDA approval
- 15 because there was one study that was positive
- 16 that Berger and I were part of called PROACT 17 II published in 1999.
- 18
 - I don't know of any intra-arterial
- 19 tPA studies going on, even though it's still
- 20 an arrow in the quiver, I think, for rescue.
- 21 The new guys, the young ones, are very, very 22 quick with these Solitaire stent retriever
- 23 devices.
- 24 So what Berger used to do in six
- 25 hours, they do in 15 minutes. It's

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- considered, recommending consideration of
- that option. That's why I asked if it's --
- time has passed as far as the leading
- 4 thinkers in the field?
 - Well, not thinking that I'm
- 6 leading, the guidelines that you had had us
- review were developed very, very quickly
- after the stroke meeting that happened to be in Nashville in February of '15, because MR
- 10 CLEAN had been published in December '14.
- 11 And it was a sea change in terms of
- 12 the leading minds at that time. So very, very quickly in January of '15, you know,
- 14 this quick recitation of lightening had
- 15 struck, the Earth had shaken, there was
- 16 something new to do. And the other studies
- 17 had all been stopped once MR CLEAN was
- 18 published in the New England Journal. Those
- 19 studies were far from incomplete. Even
- 20 though they were stopped prematurely, they 21 were all positive.
 - Q. Right.
- 23 Α. And so once the guideline group had
- 24 a chance to rewrite the guidelines, which
- 25 took them until late 2017, though the current

ALFRED CALLAHAN, III, M.D. RUFFINO vs ARCHER

	<u>_</u>				
1	Page 121 2018 quidelines do speak a bit irreverently,	1			Page 123
2	but say there's still scientific reason to do	2	I, ALFRED CALLAHAN, III, M.D., do		
3	what the old dinosaurs like me did in another	3	hereby certify that I have read the foregoing		
4	century. So I'm grateful that their memory	4	deposition transcript and find it to be a		
5	has returned.	5	true and accurate transcription of my		
			testimony, with the following corrections, if		
6	MR. GIDEON: Dr. Callahan, always	6		ony, with	the following corrections, if
7	good to see you. Thank you very much for	7	any:		
8	answering my questions.	8			
9	THE WITNESS: The pleasure is mine,	9	PAGE	LINE	CHANGE
10	sir. It's great to see you again.	10			
11	MR. WITT: I don't have any	11			
12	questions.	12			
13	MR. CUMMINGS: No questions.	13			
14	(Whereupon, the above-mentioned	14			
15	document was marked as Exhibit No. 10 to the	15			
16	testimony of the witness.)	16			
17	(Whereupon, the deposition was	17			
18	concluded at approximately 3:06 p.m.)	18			
19		19			
20		20			
21		21			
22		22			
23		23			
24		24			
25		25			Alfred Callahan, III, M.D.
-	Page 122				
1	CERTIFICATE				
2	STATE OF TENNESSEE)				
3	(COLDINAL OF DIMINISTRADO				
4	COUNTY OF RUTHERFORD)				
5	I, STEPHANIE A. FAULKNER, LCR, CRI,				
6	CPE, CERTIFY:				
7	The foregoing proceedings were taken before me at the time and place stated in the				
8	foregoing styled cause with the appearance as noted.				
9	noted.				
10	Being a Court Reporter, I then reported the proceedings in Stenotype, and				
	the foregoing pages contain a true and				
11	correct transcript of my said Stenotype notes then and there taken.				
12	I am not in the employ of and am not				
13	related to any of the parties or their				
14	counsel, and I have no interest in the matter involved.				
15	I FURTHER CERTIFY that this				
16	transcript is the work product of this court reporting agency and any unauthorized				
	reproduction AND/OR transfer of it will be in				
17	violation of Tennessee Code Annotated 39-14-104, Theft of Services.				
18	Witness my signature, this, the 20th				
19	day of April, 2018.				
20					
21					· · · · · · · · · · · · · · · · · · ·
22	At a. A. Oh				
22 23	Stickou & Fauller				
22	Stephanie A. Faulkner, LCR, CRI, CPE LCR No. 323, Expires June 30, 2018				